

Centers for Disease Control and Prevention  
and  
Centers for Birth Defect Research and Prevention

## **National Birth Defects Prevention Study**

### **Question-by-Question CATI Interviewer Instruction Manual**

**May 23, 2001**

**Revisions for CATI Version 3.092 and 3.10  
(Hardcopy Questionnaire 2/19/01)**

**National Birth Defects Prevention Study**

**Question-by-Question CATI Interviewer Instructions**

**TABLE OF CONTENTS**

<b>I.</b>	<b>INTRODUCTION.....</b>	<b>4</b>
	A. Background	
	B. Interviewer Instructions	
<b>II.</b>	<b>GENERAL INSTRUCTIONS .....</b>	<b>5</b>
	A. What and How to Read	
	B. Completing Responses	
	C. Editing	
	D. Coding Conventions	
	E. Legitimate Probing	
<b>III.</b>	<b>SETTING UP THE INTERVIEW .....</b>	<b>9</b>
	A. Prepare Necessary Materials in Advance	
	B. Call List Screen and Contact Forms	
	C. Pregnancy Calendar and Time Periods	
	D. To Begin the Interview	
	E. Handling Technical CATI Errors and “Freezing”	
	F. Opening Spanish Version of CATI	
<b>IV.</b>	<b>QUESTION BY-QUESTION INSTRUCTIONS .....</b>	<b>14</b>
	A. Section A: Establishing Dates	
	• Intro Script	
	B. Section B: Maternal Health	
	• General Instructions About Maternal Health	
	• Specifications for Questions About Maternal Health	
	C. Section C: Pregnancy History and Fertility	
	• General Instructions About Pregnancy History	
	• Specifications for Questions About Pregnancy History	
	D. Section D: Supplements (Specifications)	
	E. Section E: Tobacco (Specifications)	
	F. Section F: Alcohol (Specifications)	
	G. Section G: Substance Abuse (Specifications)	
	H. Section H: Home Environment (Specifications)	
	I. Section I: Mother’s Occupation (Specifications)	
	J. Section J: Father’s Occupation (Specifications)	
	K. Section K: Family Demographics (Specifications)	

	<b>Water Module (Sections L through P):</b>	57
	General Instructions for Water Module	
	Background and Rationale for Water Module	
L.	Section L: Home Water Environment	
M.	Section M: Drinking Water at Home	
N.	Section N: Drinking Water at Work or School	
O.	Section O: Home Water Use Activities	
P.	Section P: Swimming Pool Use	
Q.	Section Q: Closing	
R.	Section R: Status of Interview	
S.	Section S: Interviewer Remarks	
V.	<b>AFTER THE INTERVIEW:</b>	68
VI.	<b>ATTACHMENTS:</b>	69
	<b>A. KEY COMMANDS LIST</b>	
	<b>B. INFERTILITY PRIMER</b>	

## **National Birth Defects Prevention Study Question-by-Question CATI Interviewer Instructions**

### **I. INTRODUCTION**

#### **Background**

Birth defects are the leading cause of infant mortality in the United States, accounting for about one fourth of all infant deaths. Most causes of birth defects are unknown. The Centers for Disease Control and Prevention (CDC) is sponsoring the Centers of Excellence to provide surveillance, research, services, and evaluation aimed at prevention of birth defects. This questionnaire is one part of the CDC's special effort to identify causes of birth defects. It has been carefully designed with the input of many scientists across the country, and has been pretested with women who recently gave birth. The questions ask about family, health, occupation, lifestyle, smoking, drinking, and exposures to chemicals and drugs. Many groups involved in birth defects epidemiology research are using the questionnaire. The contribution that you make on each and every interview is critical to the success of this project as well as the other birth defects projects that will be collaborating with us.

This questionnaire is being conducted as a computer assisted telephone interview (CATI) that was developed in Access, a Microsoft software program.

#### **Interviewer Instructions**

Consistency of data collection and documentation must be maintained across the multiple studies collaborating in the Centers of Excellence program. Carefully following the interviewer instructions is a crucial mechanism for achieving this consistency. Instructions can be edited and updated at any point during the studies. Any member of the study staff, interviewer, coder, supervisor, or study coordinator, can discover and report that an issue needs clarifying as the study runs. If any addition or change is made, the improved version of the instructions will be identified by its date, and revised pages or new versions of the manual will be distributed. Instructions are used not only to facilitate the implementation of a study but also to document how the study was conducted for posterity.

## II. GENERAL INSTRUCTIONS

### A. What and How to Read

The top of each CATI screen shows the general topic being addressed by the questions on the screen, such as “Maternal Health-Respiratory Illness” or “Respiratory Illness Details.” These headings appear in a large font and black regular case type. The subject’s pregnancy calendar also appears at the top of CATI screens for easy reference.

Questions and scripts to be read to the subject are in regular upper and lower case print. Because it is important that each question be asked the same way, interviewers should read the questions as written and use only approved probes; they should not change the wording of items. Instructions to the interviewer, not to be read to the subject, are in caps in brackets and/or in blue type. For example, do not read instructions such as [READ LIST]. Never read “don’t know” (DK) or “refused” (RF) options to the subject.

Words that need to be substituted by the interviewer are in parentheses, e.g. (Name of Index Baby or NOIB). A slash is used for alternate genders or words to be read to the subject, such as “s/he” or “is/was”. A slash also is used for alternate questions to be read, for example, “What did you take?/Did you take anything else?” Select the appropriate gender, word, or question based on the circumstance.

Lists of responses should be read when the script of the question implies that items are forthcoming, for example, “Did you take...? Accutane, Aspirin, Ativan,...” etc. The items are read as a list, with a short pause and inflection after each, indicating that you expect a YES or NO response. Obtain a response for each item on the list. Other items require the subject to select only one response from a list of mutually exclusive options. Again, read the response options as a list, but, instead of waiting for a response to each, continue reading all of the options so that the subject will select the most appropriate response. Read all of the mutually exclusive options before accepting a response.

Throughout the questionnaire, when lists of items or responses are read, the CATI generally proceeds down the list of items or categories (e.g., first requiring the interviewer to record a YES or NO response for each medication in a list). The CATI then may guide you to a series of questions or a table to obtain more details about each item that had a YES response.

In general, when questions are in table format, the CATI program proceeds from left to right. The CATI will guide you to ask questions from left to right to complete the first row; then it will go to the next row. At each subsequent row, ask the same string of questions written at the top of the columns. Subsequent rows may address different illnesses or medications, or different numbers of the same types of experiences.

Skip patterns refer to questions that are skipped over because they are not applicable. Usually, there is a lead or “gateway” question asking if the subject ever had a particular condition or ever experienced a certain event, and requiring a simple YES or NO response. For example, the lead question may ask if the subject ever had a particular illness or job. If the answer is NO, the questions about that illness or job are skipped. Usually, the CATI program will automatically skip to the appropriate items; thus, the interviewer will not see the questions and screens that are skipped. Nevertheless, interviewers should be aware of the appropriate patterns of skips, and should report any deviations to the supervisor after completing the interview. Use a pen and notepad to record such problems during the interview. Reviewing the hardcopy instrument will provide an overview of the entire instrument and skip patterns. (Note: The hardcopy shows skip patterns in brackets or parentheses to the right of the response/code to which the skip applies. For example, if the response to item B1 is “no,” then NO....2 [B14] means circle 2 and skip to question B14.)

Speak loudly enough to be heard, with a natural conversational tone. Balance sensitivity and warmth with professionalism and objectivity. Read each time as if you are asking the questions for the first time (but, at a higher comfort level), so that you will sound interested and not monotonous. Although the questions are the same, each subject's experiences are unique.

## **B. Completing Responses**

Interviewers may use the "mouse" and/or keyboard commands to move around in the CATI system. Also refer to the "Software User Guide" prepared by Slone Epidemiological Unit and the List of Keyboard Commands in **Attachment A** of this manual.

Usually, interviewers should **use the "TAB" key as the preferred way to proceed to the next item or page.**

When you have completed all information on one screen, using "TAB" should proceed to the next appropriate screen. In many circumstances the "Enter" key appears to work the same way; however, the "TAB" key is preferred because it consistently and accurately records the information. Failure to use the "TAB" key can result in incomplete or inaccurate recording of information in the database, and can produce incorrect skip patterns. To exit some screens such as Medication Detail screens, interviewers must click the "Exit Door" (or "Close Form") button in the upper right corner to close the screen. When entering notes under a "Comment" button, interviewers should press "TAB" after typing the text and then click the "Exit Door" (or "Close Form") button for the comment box.

Interviewers will type responses into boxes or will select responses by highlighting options on pull-down menus. Use the mouse to open the pull-down menus by clicking the arrow attached to the response box. Or, use key command F4 to view the pull-down menu. Select (highlight) the appropriate response option from the list. Alternatively, typing the first characters of a particular option into the box will automatically select that option from the menu. Use "TAB" (or "ENTER") to enter the response.

For most medication items in the questionnaire, interviewers will type the names of specific medications or remedies into the response boxes, or will select medications by highlighting options on pull-down menus or "short lists." A comprehensive Drug Dictionary (developed at the Slone Epidemiology Unit of Boston University) is available as pull-down response menus for most medication items. The Slone Drug Dictionary lists medication names alphabetically. The list includes prescribed and non-prescribed (OTC) medications and some herbal remedies. It is easiest to begin typing the name of the drug in the response box; the CATI will automatically find potential items on the list. Or, select the appropriate drug name by highlighting it and then pressing "TAB." If the name of the medication is not known, but the type of medication is known, type "NOS" and then select (highlight and "TAB") the appropriate type of medication from the list. A list of all **NOS medications** in the Slone Drug Dictionary appears in the Interviewer Manual Notebook in Section 7 (Coding Instructions). Some of the medication menus include "**short lists**" of medications to read as probes. To select medications directly from these short lists, highlight the medication and then click the large arrow. (Refer to the Slone "Software Users Guide" in Section 2 of the Interviewer Manual Notebook for instructions on Medication Prompt lists.)

If you do not use correct methods to change or delete information, the CATI program may not skip properly and may include incorrect or "missing" information in the database. Merely backspacing over incorrect information will not remove it. (Although the space appears empty, information may not be erased.) To change a response or correct an error in recording a response, backspace over the incorrect text, type in the correct response, and then press "TAB" to enter the new information. The following method is the preferred way to erase a "record row" (to avoid creating missing information in the dataset).

First, use the mouse to click the gray square or selector bar on the left-hand side of the record; this will highlight the whole row of information. Then, **press the "DELETE" key to erase all of the**

**information in the record.** (Refer to the Slone “Software Users Guide.”)

The Slone Users Guide also explains how to restore an answer that was just entered. Before leaving the text box, press the Escape (Esc) key. The previous answer will be restored. By pressing the Esc key twice, the entire page will be restored to previous values; do this before leaving the page.

We encourage interviewer comments concerning difficult or complex answers. If responses are longer than the box or lines provided, use the “Comments” button for the item or at the bottom of the screen to record additional details or comments. Before pressing the Comments button, be sure the cursor is in the response box for the item to which the comment should apply. Within the Comment box, identify the item to which the comment applies as part of the text. (Press “TAB” after typing the text, then click the “Exit Door/Close Form” button for the comment.) The interviewer also may use a notepad to record handwritten notes and comments during the interview. Again, be sure to note the question number or screen to which the comments apply. In the newer versions of the CATI, yellow highlighting appears in fields that have a comment associated with them.

If a subject gives a response and neither of you is certain of the spelling, type it phonetically and also type a “(ph)” next to it so that the editors will know that it is an attempt. You may also indicate that a subject gave a “best guess” response by typing “(BG)” next to the response.

### **C. Editing**

Because the CATI program automatically performs editing routines while the interview is being conducted, only minimal editing should be necessary after the interview. After the interview is completed, only the study supervisors may re-open an interview to make editing changes. However, a crucial part of your role as an interviewer is to review and edit your handwritten notes and comments about the interview immediately following the interview and to alert your supervisor about any problems and corrections or further steps to be taken. You may be able to simply make your handwriting more legible. Your notes should explain any difficulty in recording information and potential problems with skip patterns. Carefully note any missing data or information that needs clarification, and state the need to re-contact the subject to clarify responses or obtain missing data. We will appreciate any comments you add to help supervisors, editors, and coders interpret or understand something unusual.

To correct missing information or errors that require information from the subject, you will need to telephone the subject again. We prefer that the same interviewer make callbacks to the subject, so that she does not get the impression that there are lots of people examining or viewing her data. The supervisor will enter any actual corrections into the CATI interview.

It is best to review and edit your notes immediately after completing the interview. Responses from more than one subject can become confusing very quickly. You must review while a participant’s interview is fresh in your mind, and must not interview another until you have edited the previous one.

### **D. Coding Conventions**

The CATI program automatically applies most codes when the interviewer selects responses. It automatically assigns medications codes using the Slone Drug Dictionary, a computerized system developed at the Slone Epidemiology Unit of Boston University. Codes to open end responses, such as birth defect diagnoses and comments fields, will be applied later by trained coders.

This CATI questionnaire uses the letters “DK” to indicate “don’t know” responses. Type “DK” or “dk” (either in caps or lower case) in the response boxes, indicating that the respondent said she did not know the answer. You may also select the DK or DON’T KNOW option from the pull-down menus. Any part of a date can be a DK; for example, November, unknown day, 1964 would be recorded and coded as 11/DK/64.

In general interviewers should not easily accept “don’t know” responses and should probe or use legitimate cues to help respondents give answers. A “best guess” recorded with the notation “(BG)” is usually better than a “don’t know” response.

The letters “RF” represent refusals. Type “RF” or “rf” (either in caps or lower case) in the response boxes, or select the RF or REFUSED option from the pull-down menus. Letters mailed to the subjects and approved scripts state that subjects do not have to answer questions if they do not wish to. Even in an unusual situation, if there is not an RF code available to select, you may type in an RF code to document that someone refused to answer. Of course, at times you may gently remind subjects that responses are confidential, and that answers will be grouped.

This CATI has no codes to indicate that data are missing. The CATI program will identify missing data as the interview is conducted. It will produce a Warning Box that alerts the interviewer that certain data are missing and that prompts the interviewer to obtain and record the information. For some items, interviewers cannot override the warning and must complete the missing information. Other times, the interviewer may choose to override the warning by clicking the appropriate box. The CATI program will keep track of items that contain missing information for which the interviewer did not indicate a response. Prompt review of your notes about missing information after the interview should alert you to situations where follow-up is necessary to obtain additional information. Some missing information might be unavoidable, for example, if a subject refuses to complete the remainder of an interview or is lost to follow-up after a partial interview.

When the subject gives a range of numbers as a response to a question requiring a frequency, the interviewer should probe by asking the subject to choose one number from the range she gave, or give her “best guess”. For example, if the subject reports taking a medicine 3 or 4 times, ask “Would you say 3 or 4? What is your best guess?” (We do not use a convention such as using the midpoint of the subject’s response.) If a pattern of using a particular medication changes in a clear pattern (e.g., tapers off), use multiple rows to record the dates and different levels of use. Use the Comment or Memo field to record details about an ambiguous pattern or to clarify the usage pattern.

The CATI refers to trimesters as T1 (first), T2 (second), and T3 (third) trimesters. It refers to time periods from B3 (-3 months, or 3 months before conception or pregnancy) to P10 (10<sup>th</sup> month of pregnancy). See below Section IIC describing Pregnancy Calendar and Time Periods.

## **E. Legitimate Probing**

Throughout the question-by-question instructions, there are suggestions for acceptable kinds of probes. You must think of standardizing your use of probes (by question), so that you always use a similar “legitimate” probe when a subject hesitates or at first replies with a DON’T KNOW. On days when you are tired or not feeling your best, it is paramount to remember how important it is to treat all subjects as uniformly as possible to keep their data comparable. For example, a probe used for question X should be used consistently for all subjects needing a probe for that same question.

Have a calculator at hand to help subjects calculate dates. You must help the mother by using only information she has given, and by proceeding with logical conclusions. For example, she may say her father died when she was very young and she does not remember the date. You may ask, “About how old do you



think you were?” If she answers, “about seven,” you would add seven to her birth year to get the father’s year of death, as you explained your calculation aloud. Then you would ask if she agreed with the calculation before recording it. Because she could not remember the month and day, you would fill those with DKs for DON’T KNOW. For example, if the subject was born in 1965 and her father died when she was 7, the data recorded would be DK/DK/72.

Refer to the Basic Interviewer Manual for general probing guidelines. The item-specific instructions provide guides for probing particular questions.

### **III. SETTING UP THE INTERVIEW**

#### **A. Prepare Necessary Materials in Advance**

Have ready the following materials when you begin the computer assisted telephone interview.

- Interviewer Instructions and Manual
- Introductory and Oral Consent Scripts
- Contact Logs and Other Forms (if relevant for your study)
- Notepad and pen
- Calculator
- Watch (if needed to time contacts or the interview)
- Hardcopy Instrument (for emergencies only when at least 75% of interview is complete)

#### **B. Call List Screen and Contact Forms**

Review the information about the subject on the Call List screen of the CATI. (See Example Screen in this manual. Refer to the instructions about the Call List Form in the Slone software guide.) The Call List screen records the following information.

- Subject’s ID Number (preassigned);
- Subject’s Name, Telephone Numbers, and Address;
- Phone Log and Number of Phone Calls (to the subject, thus far);
- Baby’s First Name (enter “the baby” if stillbirth);
- If Baby is “TAB” (therapeutic abortion) or stillborn/deceased;
- Baby’s Due Date (estimated by study investigators from medical records);
- Language Spoken;
- Call Date and Time, and Type of Call (e.g., Scheduled or Call-back);
- Schedule Comments;
- Final Outcome; and
- Boxed Space for Notes.

Enter the baby's first name in the box provided. CATI will use this information to personalize questions throughout the interview. If the baby was not named (e.g., stillborn or TAB babies), enter "the Baby" (or "the Baby Girl/Boy") in the box.

Click on the phone icon to record the date, time, outcome of call, and comments (include interviewer ID or name). Double clicking the Call Date response box provides a reference calendar; double click on the appropriate date on the calendar to enter the appointment day. Use the Notes box (on the right-hand side of the Call List screen) to provide information useful to other interviewers for scheduling or conducting an interview with the subject. Notes may document special circumstances pertinent to the interview, for example, concerning family structure or the death of the baby.

Before calling the subject, check that you have waited 10 days (for regular U.S. mail) since the mailing of the advance cover letter. (If the advance letter was sent by express mail, allow at least one day after delivery for the subject to review the materials.) Having entered the subject information in the Call List and other appropriate tracking logs for your study, enter the day, date, and time of your attempt to contact the mother by telephone in the Call List.

When the subject is willing to begin, select (click) the "Start Interview" button (at left of Call List entry for the subject), and proceed to conduct the interview. After the interview, record your Study Interviewer ID number and complete the Interviewer Remarks. Also, record the appropriate outcome in the "Final Outcome" box of the Call List screen. If you completed the interview entirely, select the "Interview Completed" outcome. If the interview was only partially completed and subsequent sessions are needed, select "Interview Started/Not Completed" in the Outcomes box. The options in the Final Outcome box include:

- Interview Completed
- Excluded, Contacted
- Refused
- No Contact
- Unable to Interview on Time
- Excluded/Medical Record Review
- Interview Started/Not Completed
- No Phone
- Excluded, No Contact
- Excluded, Completed
- Pilot Test

The contact and clarification calls made for editing purposes should not be documented as Interview Sessions, and should not be included in fields for Number of Sessions or Total Length of Interview. Clarification calls should be documented on your study's contact logs or call record forms. Document important clarifying information or changes in identifying information (e.g., names, telephone numbers, and unusual circumstances) and the outcome of each call on the relevant contact logs for your study.

### **C. Pregnancy Calendar and Time Periods**

The Pregnancy Calendar will be available for easy reference throughout the interview. To open the subject's Pregnancy Calendar within CATI screens, select (click) the "Pregnancy Calendar" button at the bottom left of the screen. The Calendar will appear at the top of all relevant CATI screens. Move the open calendar to a different position by clicking and dragging on the top bar. Close the calendar by clicking the "X-square" in its upper right corner. We recommend that you keep the calendar open during the entire interview.

Before conducting the interview, you will review the subject's Pregnancy Calendar. The CATI will calculate the Pregnancy Calendar from the baby's birth date (A1) and due date (A2) reported by the mother. You may probe by asking the mother to give the specific day or her "best guess" (BG) for the due date; if she does not recall, ask "Do you remember if it was the beginning, middle, or end of the month?" If the mother still does not know the baby's due date (A2), click the box, and CATI will use the estimated due date (from the Call List screen) that was computed by your study investigators. Consult your supervisor if the Call List screen does not provide a due date. (See CATI Section "Establishing Dates" below.)

Notice the sequential months from -3 to 10 (or greater). Many items within the questionnaire will refer to the months from -3 (i.e., 3 months before conception) to 10 (i.e., the date of infant's birth date or DOIB). Read these as actual months, days, and years. For example, ask questions about one month from November 10, 1998 to December 8, 1998, or about the year from November 10, 1998 to October 5, 1999. The subject also may refer to months within her pregnancy such as her "second month" or to trimesters such as her "first trimester". The CATI pregnancy calendar shows the correspondence among the months, trimesters, and actual dates. (See Example Pregnancy Calendar Screen.)

Some pregnancies will last less than 9 months. In these cases, fill any non-applicable time periods with "No".

Trimesters of pregnancy are labeled as T1 (first), T2 (second), and T3 (third). The following labels identify other monthly time periods.

- B3 (-3 Month, or 3 months before conception or pregnancy)
- B2 (-2 Month, or 2 months before conception or pregnancy)
- B1 (-1 Month, or 1 months before conception or pregnancy)
- P1 (Month 1, or 1<sup>st</sup> month of pregnancy)
- P2 (Month 2, or 2<sup>nd</sup> month of pregnancy)
- P3 (Month 3, or 3<sup>rd</sup> month of pregnancy)
- P4 (Month 4, or 4<sup>th</sup> month of pregnancy)
- P5 (Month 5, or 5<sup>th</sup> month of pregnancy)
- P6 (Month 6, or 6<sup>th</sup> month of pregnancy)
- P7 (Month 7, or 7<sup>th</sup> month of pregnancy)
- P8 (Month 8, or 8<sup>th</sup> month of pregnancy)
- P9 (Month 9, or 9<sup>th</sup> month of pregnancy)
- P10 (Month 10 or greater, or 10<sup>th</sup> month of pregnancy, or greater)

## **D. To Begin the Interview**

When the study subject answers the telephone, introduce yourself, and identify your company or institution by following the scripts approved for your study. Confirm that the subject received the advance letter, brochure, Human Subjects Fact Sheet, calendar, and Food Frequency Response Guide. You must read your study's Oral Consent Script before beginning the interview. Reiterate or describe the study and confidentiality measures as needed, then invite the subject to participate.

Interviewers must always be prepared for the possibility that the baby has died. In this circumstance, offer sincere sympathy. Then tell the mother that she would be a valued study participant, and ask if you may interview her. If she refuses or hesitates, indicate that you would like to call her back in another month or longer to determine whether she feels like being interviewed at that time. Again, refer to the scripts approved for your study.

If the mother hesitates because of the time commitment, suggest that you perform the interview in sections (for perhaps 10 to 15 minute intervals, or until she indicates a stopping point). Try to find a relatively convenient day, time, and time interval for her. If the mother hesitates because of the sensitivity of the issue, be empathetic, yet emphasize the confidentiality of her responses. Indicate that answers will be grouped, and that names and other identifying information will not be used by the researchers. Also emphasize the importance of the study and her role in it: we need to learn more about the causes of birth defects in order to prevent birth defects in the future.

When the subject has given consent, you may proceed to the first section in the CATI interview, Establishing Dates. It will begin with the Introductory Statement.

Remember, you will want to move along as quickly as possible to avoid the eventual fatigue of your respondent. However, it is important to give her time to think, or jog her memory, to get the most accurate information. This balancing of purposes depends on the judgment and skill of the interviewer.

**Emergency Interviews with Hardcopy Instruments:** Interviewers should only use the hardcopy survey under emergency situations when the interview is almost completed (at least 75% complete). When there is a problem with the CATI, the interview should be rescheduled, whether for the entire interview or to complete a partial interview. We highly discourage sites from conducting interviews with the hardcopy questionnaire because it has not been piloted, it is not regularly updated with CATI changes, it has not been formatted for interviewing, and interviewers are not trained to use the hardcopy survey. (Only in dire circumstances such as a mother who refuses to reschedule for another time would the entire hardcopy survey be used, for later entry into the CATI.)

**Pregnancy Calendar Calculations for Hardcopy Interviews:** In the future, CDC will provide formulas or charts (based on the internal CATI program) that interviewers can use to calculate the pregnancy calendar dates. These may be used in case of power failures or other circumstances when the interview must be completed with the hardcopy questionnaire. In addition, CDC may program a CATI option to print the pregnancy calendar at the beginning of the interview, after the CATI has calculated the calendar, for use in emergency situations.

## **E. Handling Technical CATI Errors and “Freezing”**

Interviewers sometimes experience run time errors, slowness, or “freezing” of the CATI during interviews. Sometimes the errors and freezing seem related to moving backward frequently during the interview to add or correct information when the subject changes her mind. One method to get “unstuck” or to move on when the CATI freezes is to close out the interview, go back to the Switchboard and/or Call List, and then re-open the interview. Interviewers should document the circumstances of any errors, slowness, and freezing and report these to their Supervisor for attention of the CDC programmer. Center programmers may examine their networks, hardware, and machines to be sure they have enough memory. Compressing the database may decrease slowness.

## **F. Opening Spanish Version on CATI**

How do interviewers access the Spanish translation of the CATI for interviews? The most foolproof way to operate the Spanish CATI is to open the CATI interview to the first CATI screen (i.e., the opening screen “Establishing Dates”), then open the menu box at the bottom right-hand corner of the first CATI screen, and select “Spanish” from the pull-down menu.

The CATI automatically re-sets to “English” after you close the interview, so if you re-open an interview you will usually have to re-set it to “Spanish”.

## IV. QUESTION-BY-QUESTION INSTRUCTIONS

Question-by-question instructions are written for items that need clarification. Straightforward questions are not addressed. For your information and to help you avoid forgetting to read a script, the CATI includes the scripts that lead into questions just in front of the questions.

Please understand that throughout the questionnaire we use language that sounds casual and conversational. Questions may not always reflect correct grammar, but are meant to sound “natural.” Thus, you may notice that some sentences end in prepositions and use redundancies and incorrect antecedents.

### SECTION A: ESTABLISHING DATES

**A1, A2, A3:** The CATI questionnaire begins with the section “Establishing Dates.” Begin the interview by reading the “**Opening Statement**” on this CATI screen (or read the opening statement approved for your study). Then ask the first three questions (A1, A2, and A3) that establish important dates for the interview.

**A1 to A3:** Type these dates using numbers that correspond to months (e.g., 1 for January, 2 for February) and days (from 1 to 31). Type the last 2 digits of the year, e.g., “97” for 1997. Use slashes between the numbers. For example, if the subject was born on June 9, 1970, type “6/9/70” in the box next to that question (A3). For these items, it is not necessary to type leading 0s or the 4-digit year; the CATI program automatically adds leading 0s and the full year, e.g., 06/09/1970.

**A1, A2:** These items have alternate wording for mothers who had a therapeutic abortion (i.e., noted as a “TAB” baby). For stillborn babies who were not named, interviewers will substitute the phrase “the baby” for name of the index baby here and throughout the interview.

The CATI will automatically calculate the subject’s **Pregnancy Calendar** from the baby’s birth date (A1) and due date (A2) provided by the subject. If the mother does not know the due date (A2), the CATI will use the predetermined due date from the Call List screen to calculate the Pregnancy Calendar. Note that three dates from the subject’s Pregnancy Calendar automatically appear at the top of the screen, i.e., “-3 months”, “Pregnancy Start”, and “EOP/DOIB”. The full Pregnancy Calendar also will be available for easy reference throughout the interview at the top of CATI screens.

**A2:** When a doctor has given the mother more than one expected due date (EDD or expected date of delivery) for the baby, interviewers should **probe** for and record the **latest** or most recent date that the doctor provided. This applies even when the doctor revised the EDD within a week or so of the delivery. This follows the EDD protocol that CDC developed and distributed to sites.

If the subject does not know the date her baby was expected to be born (**A2**), click in the box labeled “Due Date Unknown.” First you may probe by asking the mother to give the specific day or her “best guess” (BG) for the due date. If she does not recall, ask “Do you remember if it was the beginning, middle, or end of the month?” If the mother still does not know the baby’s due date, click the box, and CATI will use the estimated due

date (from the Call List screen). **Consult your supervisor if the Call List screen does not provide a due date and the mother cannot guess the date. CATI must have a due date in order to calculate the calendar; do not attempt to conduct an interview without the calendar.**

**Note for Supervisors When EDD is Missing:** For sites that have access to vital records, Last Menstrual Period (LMP) information and gestational age by clinician exam may be available. These sources could be used to determine EDD (according to the EDD protocol) when the information is not available in the medical record. When sites cannot provide an Estimated Due Date (EDD) from the baby's medical records, then the index baby's Date of Birth (DOIB) may be substituted if the infant was full-term. DOIB should not be substituted for conducting the CATI when the baby was not full-term.

- A4:** For biologic father's birthdate, separate boxes are provided for the month, day, and year (allowing more flexibility to record "don't know" responses). If you get a DK response for the father's DOB, there is a probe to ascertain whether just the DOB is unknown, or if the father is unknown. If the father is unknown, questions about him will be automatically skipped by the CATI.
- A5:** This question ascertains the number of babies in the index pregnancy, i.e., whether NOIB was a multiple birth baby. It includes stillbirth and TAB babies.
- A6, A7, A8:** These items are not asked about stillbirth or Therapeutic Abortion (TAB) babies. A6 establishes whether the index baby is still living. If yes, then skip A7 and A8. For index babies who have died, A7 requests the cause of death, while A8 obtains the age at death for the index baby. (This information is not collected about any siblings from multiple birth index babies.)

**Options for Age of Baby When Died (A8):** CATI currently does not accept numbers greater than 31 days (range is 1 to 31) as a response for baby's age at death. Interviewers should work with the subject to re-calculate the mother's response into weeks, months or years when necessary. In the future, CDC may modify the CATI to accept any number of days as the answer. If the baby lived less than 24 hours, the response less than 1 day can be recorded as 1 day.

Although sometimes awkward, the question asking if the baby is still living must be retained. (Some mothers with living infants may think the item is silly, and it may be painful for mothers whose babies died.) The CATI does skip this item for TABs and stillborn babies. It is OK for interviewers to know whether or not the baby died; interviewers do not need to be blinded to the death of a baby.

## **Intro Script**

The next screen is the "**Intro Script**." Read the Intro Script on the CATI screen (or read the Intro Script approved for your study). This introduction mentions the overall time period (from month "-3" to the DOIB or infant's birth date) of the interview. It also gives general instructions about how to respond to medication items throughout the questionnaire. Notice that the instructions tell the subject to include "any and all" medications and remedies that were prescribed by a health care practitioner; obtained

without a prescription from pharmacies, friends or relatives; and herbal or home remedies. Throughout the survey, interviewers must record all prescribed and non-prescribed (e.g., over-the-counter or OTC) medications, and herbal remedies reported by subjects.

Click the box in the lower right-hand screen after you have read this script to the subject.

## **SECTION B: MATERNAL HEALTH**

### **General Instructions About Maternal Health:**

- Remember to look at the Pregnancy Calendar and phrase time periods in questions in terms of the actual months, days, and years. For example, in questions that include the full time period “between (-3) and (DOIB)s”, you may say “between May 1998 and April 1999” to indicate the time from May 20, 1998 through April 2, 1999. However, for a specific month within the time period, state the full month, day, and year, e.g., “from May 20, 1998 to June 19, 1998.” For baby’s birth date (DOIB), you also should substitute the actual birth month, day, and year, for example, April 2, 1998.
- When you see (illness), say the name of the illness in question. When you see (medicine), say the name of the medication or remedy in question.
- **Medicine and Remedy Lists:** When CATI specifies instructions such as [READ LIST], read lists of medicines in their entirety. Some lists are read only as prompts to subjects who have difficulty remembering. Many questions include pull-down menus containing the entire Slone Drug Dictionary from which medications can be highlighted and selected. Of course, you never read the entire dictionary, but the CATI may direct you to read short lists of medications as probes. For example, the following instructions may appear “IF CAN’T RECALL, READ FROM DRUG LIST. Did you take....” To select a medication directly from the short list, highlight the medication and click the large arrow. Instructions for using the Drug Dictionary appear above in Section IIB (General Instructions, Completing Responses).
- For open-end questions about medicines and remedies, the CATI provides multiple empty spaces or boxes for recording drugs taken for a given illness. Usually you will record the drugs in the order reported by the subject. However, you may record the drugs in any order. For example, if the subject changes her response or you must correct recorded data, you may delete a record in the middle of a list and replace the information with a different drug.
- For easy reference during the interview, the “Medications Use” button at bottom left of the screen keeps a summary of all medications taken during the interview.
- Practice until you are comfortable with the pronunciation of the illnesses and medications before you begin interviewing subjects.
- The format sometimes requests that you SELECT FOR EACH MO (time period, medicine, etc). A YES or NO response or code must be selected for each time period, medicine, etc. When you have gained some experience, you may select the YES codes first, and then click the “Fill all remaining with NO” button. The latter step will save time during the interview, but you must be very careful to first select the correct YES codes.
- On table-formatted questions, when you repeat the same questions for the first, second, and third (etc.)



subrecords, you will read the alternate script indicated by the slash, e.g. “What kind of illness did you have the 1<sup>st</sup>/2nd/3rd time?” Often, CATI will prompt you to do this.

- Generally, on table-formatted questions that request lists of medicines taken, you should fill the boxes or spaces from top to bottom. On the other hand, you generally should fill the details about each medicine in the rows from left to right. You should not leave blank boxes, rows, or records. If you leave a blank record, the computer may interpret the record as unacceptably missing data and may not skip properly. (Be sure to delete empty rows and records.)
- If the subject knows the complete start and end dates for taking a medicine, CATI will skip the duration question “How long did you take it?” (Complete information includes the month and year for both start and end dates; you then skip the duration question.) If the subject does not know exact or complete information about the start and/or end dates, then ask the duration question. In all of these situations, ask the frequency question “How often did you use the (medicine)?”
- When frequencies for taking medications elicit a response such as “about every other month, but I don't know which months,” our policy is to select YES for every other month beginning with the -3 Month (or B3) and continuing with B1, P2, P4, P6, P8, and P10. Stop at the birth month, and fill the alternate months with NO responses. Also write a note under “Comments” to say, “every other month, not sure which.” This may occur especially for OTC medications, for example, when the mother reports taking aspirin when she has headaches that occur every other month.
- Some questions provide alternate wording for subjects who had therapeutic abortions (i.e., noted as “TAB” babies).
- Within medication modules, use the Key Commands [ALT T] and [ALT D] respectively to switch back and forth between the Medications Taken and Medication Detail forms. Use the “Exit Door” icon button to close the forms.
- Use the scroll bars (usually on the right side) to move up and down lists of illnesses, medicines, etc.
- **Limits of Probing for Medication Details:** Interviewers should not probe for specific doses of medications, such as number of milligrams and tablets for medicines. This information cannot be used in analyses because it is not collected uniformly from all subjects. Although it won't hurt to document such details if the subject volunteers extra information, probing for additional details could lengthen the interview and give the mom the impression that she should report the details for all questions. The interview is already very long.

### **Specifications for Questions About Maternal Health:**

#### **Maternal Health--Diabetes**

- B1** This item begins with a general script (underlined) that leads into questions about the subject's health. Notice that the question asks whether the subject ever had **diabetes**, according to a doctor. The phrase “including gestational diabetes” has been added to the stem of the question.
- B2** (If YES to B1): You must read all of the response options in the pull-down menu. Responses to these questions will tell us whether the diabetes was or is gestational

(gestational diabetes can resolve after a pregnancy), insulin-dependent (Type I or Juvenile), or noninsulin-dependent (Type II or Adult).

**B3** This question asks for the month and year of first diagnosis (which can indicate juvenile or adult onset diabetes). Select a month and year from the drop down lists. (There are no response options for “infancy”, “childhood”, etc.) The CATI asks the date that the mother was first diagnosed, so if the mother had gestational diabetes in a previous pregnancy, the question could miss the date that she was diagnosed for the current pregnancy. When this happens (for multiple gestational pregnancies), interviewers should record the diagnosis date for the current pregnancy in a Comment.

**B4** Please notice that this question asks whether the respondent ever took insulin.

**B5-B7** These questions ascertain the ages or dates when the subject started and stopped taking insulin, and whether the subject took it continuously. We are interested in lifetime use, not just Pregnancy Calendar dates. For **B5** and **B7** in addition to specific ages, the pull-down menu provides codes for:

Infancy (<1 year),  
Childhood (1-12 years),  
Teenage (13-19 years),  
Young adult,  
Adult, and  
Don't know (DK).

Often when a diagnosis was made in early life, the respondent truly cannot remember when she started taking medication. Using an option for infancy, childhood, etc. is more specific than a “don't know.”

**B7 Memo** For subjects who had a more complex pattern of taking insulin in their lifetimes, record the details in the box next to the special “Memo Field” for this item. Include the month and year for each time the subject began and ended a course of insulin. This special memo field is provided because the patterns of taking insulin can be very complex and varied, and it was not possible to program the CATI to systematically document all of the possible situations and circumstances. (If you need more room, open the regular “Comments” space.)

**B8-B9** Notice that we are looking for any other medicine or remedies (excluding insulin) used for diabetes during Pregnancy Calendar months between (-3) and (DOIB).

If YES to other medicine, then click the “Meds>>>” button. CATI will open a folder called “Medications Taken.” List all medicines taken. Record one per line, in any order. First ask, “What did you take?” then probe by asking, “Did you take anything else?” to elicit a second (third, etc.) medicine taken for diabetes during the year. CATI will prompt you to do this.

Fill boxes or records from top to bottom. If only one medicine is given it should go in the first record. Do not leave blank boxes or records in the middle of the list (one blank box will remain at the end of the list). If you left the first record blank and typed in the space for a second record, the computer would interpret the first record as unacceptably missing data and may not skip properly.

There are many oral medications for diabetes. Common ones are Diabeta, Diabinase, Dymelor, Glucophage, Glucotrol, Glucotrol XL, Glynase Prestab, Micronase, Orinase, and Tolinase. The entire Drug Dictionary is available as a menu. If the subject cannot recall, read the “short list” to probe.

### **B10-B13**

After you record all other medicines in B9, click the folder labeled “Medication Details”. CATI will create a table for recording the details about each kind of medicine taken. (Insulin will not be listed.)

Ask this series of questions for each medicine, completing all questions about one medicine before proceeding to the next medicine. CATI will predetermine the order of the medicines; look for the medicine name at the top left of the CATI screen. Record the details about each medicine moving from left to right across the rows or records. If the subject had more than one episode of taking a medicine, use a different row to record the details about each episode. Then move on to the next medicine. (Again, do not leave blank rows. If you leave a row blank, the computer may interpret the record as unacceptably missing data and may not skip properly.)

As you read the questions, look at the Pregnancy Calendar at the top of the screen to see the dates -3 through DOIB. For example, when referring the entire time period, you will say, “...from June, 1998 to May, 1999 did you...?” However, for specific months, you will say the full month, day, and year, e.g., “from June 20, 1998 to July 19, 1998...”.

There is no need to tell the mom that months can be grouped (e.g., by trimesters) on the calendar. If she names any months or a particular time period, you simply select the code for the time period that her answer falls into.

If you need to move between the medication module screens, use Key Command [ALT D] to switch to switch to the Medication Details folder and [ALT T] to move to the Medications Taken folder. When you have completed all medicine questions in both folders (“Medications Taken” and “Medication Details”), click the “Exit Door” icon at the top right of the CATI screen to move to the next question.

### **B11-B12**

If the subject cannot remember the month or day she stopped taking the medication, tab through the “stop” date field and record the number of (days, weeks, months) the medicine was taken. If she can’t remember the start date, you’ll need to fill that with DKs or CATI will think the start date was missing. If she can’t recall the date she stopped the medication **or** the duration, select DK in the month and year of the “stop” date and CATI will skip over the duration.

### **B13**

If the frequency of use does not fit the coding arrangement, there are some special options available at the end of the drop down list:

- IV continuous
- IV pump
- Patch
- Schedule varied/only as needed

Interviewers should use the option “schedule varied, used only as needed” in the response menu only when the mother really does not know or cannot recall, and cannot or will not be more specific even after probing. Interviewers should **probe**

deeply to obtain the details about when (time frame) and how often (frequency and duration) the medicine was taken, and record details whenever possible. The Comments Button may also be used to record the details of what the mother said especially when the interviewer is not certain how to record/code the mother's response. For example, if the mother says she had occasional headaches for which she took some type of painkiller, the interviewer should probe to determine the time frame and how often the headaches occurred.

## **Maternal Health--High Blood Pressure**

**B14** The question asks whether a subject ever had **high blood pressure**, according to a doctor. High blood pressure is simpler language for hypertension.

**B15** This refers to age in years. The pull-down menu includes response options for infancy (<1 year), childhood (1-12 years), Teenage (13-19 years), Young Adult, and Adult (described above for items B5 and B7).

If a subject cannot remember when she was diagnosed, you may ask, "Do you remember if you were working, or where you lived at the time?" or "Was it before or after you had children?" Probes like this can help jog the memory or give some handle on a time frame from which to figure.

Unacceptable probes would be "Do you think you were in your 20s?" or "Were you over 30?" They are unacceptable because they provide answers. It is imperative not to put words in the respondent's mouth because it is so easy for them to say yes and let you do the work. Your answers are not valid data. The idea is to pull information out, not suggest it.

**B16** For "TAB" (therapeutic abortion) subjects, the CATI provides alternate wording for this question, i.e., "Did you have high blood pressure when you had the affected pregnancy?" The last phrase replaces "when you were pregnant with (NOIB)".

**B18** If your respondent does not know how to spell a medicine, write it phonetically and put a "(ph)" next to it. Some common medicines for hypertension are: Hydralazine, Propranolol, Inderal, Lopressor, Moderil, Minipress, and Tenormin. If needed, use the "short list" to probe. After ascertaining each one, fill the responses for each until the Mom replies NO to "Anything else?" You will proceed to **B19** (to obtain details about each medicine).

**B19-B20** The pull-down menus for start and stop dates list the response options for infancy, childhood, etc. that are described above for items B5 and B10.

**B20-B21** If the subject cannot remember the month or day she stopped taking the medication, tab through the "stop" date field and record the number of (days, weeks, months) the medicine was taken. If she can't remember the start date, you'll need to fill that with DKs or CATI will think the start date was missing. If she can't recall the date she stopped the medication **or** the duration, select DK in the month and year of the "stop" date and CATI will skip over the duration.

**B22** If the frequency of use does not fit the coding arrangement, there are some special

options available at the end of the drop down list:

- IV continuous
- IV pump
- Patch
- Schedule varied/only as needed

Interviewers should use the option “schedule varied, used only as needed” in the response menu only when the mother really does not know or cannot recall, and cannot or will not be more specific even after probing. Interviewers should **probe** deeply to obtain the details about when (time frame) and how often (frequency and duration) the medicine was taken, and record details whenever possible. The Comments Button may also be used to record the details of what the mother said especially when the interviewer is not certain how to record/code the mother’s response. For example, if the mother says she had occasional headaches for which she took some type of painkiller, the interviewer should probe to determine the time frame and how often the headaches occurred.

## **Maternal Health--Seizures**

**B23-B24** The first question asks if the subject ever had **seizures**. The second item (B24) asks if the subject ever had **epilepsy**, according to a doctor.

**B27** Some common medications for epilepsy or seizures are: Dilantin, Depakote, Klonopin, Tegretol, Valium, Diazepam, Carbamazepine, Chlorazepate, Phenobarbital, and Tridione. Again, practice until you are comfortable with the pronunciation of the medications before you begin interviewing subjects. If needed, use the “short list” to probe.

**B25, B28, B29** Pull-down menus for these items include the response options for infancy, childhood, etc. described above for items B5 and B10.

**B29-B30** If the subject cannot remember the month or day she stopped taking the medication, tab through the “stop” date field and record the number of (days, weeks, months) the medicine was taken. If she can’t remember the start date, you’ll need to fill that with DKs or CATI will think the start date was missing. If she can’t recall the date she stopped the medication **or** the duration, select DK in the month and year of the “stop” date and CATI will skip over the duration.

**B31** If the frequency of use does not fit the coding arrangement, there are some special options available at the end of the drop down list:

- IV continuous
- IV pump
- Patch
- Schedule varied/only as needed

Interviewers should use the option “schedule varied, used only as needed” in the response menu only when the mother really does not know or cannot recall, and cannot or will not be more specific even after probing. Interviewers should **probe** deeply to obtain the details about when (time frame) and how often (frequency and duration) the medicine was taken, and record details whenever possible. The

Comments Button may also be used to record the details of what the mother said especially when the interviewer is not certain how to record/code the mother's response. For example, if the mother says she had occasional headaches for which she took some type of painkiller, the interviewer should probe to determine the time frame and how often the headaches occurred.

## **Maternal Health--Respiratory Illness (Colds and Flu)**

**B34** This question asks if the subject had a **cold or flu** during the Pregnancy Calendar time period (from the –3 month to DOIB or DOPT).

If Mom says NO to a major gateway question that skips over a large number of questions, it is good to reiterate “No colds or flu during that year?” When you elicit a second NO by saying this, you can be sure that she was listening and that the skip to **B47** is certain.

If Mom starts to report an illness other than respiratory colds or flu, politely stop her and say this question pertains to colds and flu only, and there will be another opportunity to record the other illness she mentioned.

**B35-B46** First ask the entire series of questions (B35-B46) for the first episode of a cold or flu. If needed, CATI will create additional tables for other episodes. Repeat the series of questions for the 2<sup>nd</sup> episode, 3<sup>rd</sup> episode, etc. CATI will skip you to appropriate items in each episode. Use the “Add Respiratory Illness” button to add a new episode. Use the “Next Respiratory Illness” and “Previous Respiratory Illness” buttons if you need to move between episodes.

If Mom had multiple episodes of the same kind of cold or flu, record these in separate records. We want to be able to place the related symptoms, fevers, and medicines in the correct months.

**B35-B37** For each episode, substitute the appropriate word (first, second, third, etc.) when asking “When did your (1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>) cold or flu episode start?” Record the month, day and year of the start and stop dates for each episode of a cold or flu. If the subject cannot remember the “stop” month and day, tab through the “stop” date field and then ask the alternate question “How long did the illness last?” and record the number of days or weeks. If she can't recall the date the illness stopped or the duration, you may select DK in the month and year of the “stop” date and CATI will skip over the duration.

Use the “Add respiratory Illness” button when you need to insert an additional episode that the mother remembers later. To delete an episode of cold/flu illness, click the gray selection bar on the left side of the record. Then press the delete key to erase all of the information about that episode (including medication details). Although you should try to record the episodes in chronological order, it is not necessary that they be chronological.

**Handling Very Vague Recall of Colds/Flu:** Mothers may say something like “I’m sure I had a cold/flu, but I don’t know when” or “I usually have a cold/flu in the winter, so I must have had one.” In such situations, the mother really does not know if or when she actually had a cold. According to CDC, interviewers should not pursue a cold/flu as

an episode if it cannot be nailed down; we do not want to encourage subjects to pull information out of the air, fabricate responses, or talk in the abstract. If the mother is not sure if she had a cold/flu during the time period, interviewers should record “DK” to the gateway question, and CATI should skip the subsequent cold/flu items. Interviewers may first probe, asking “Would you say Yes or No that you had a cold or flu?” If the mother knows she had a cold/flu (or chooses Yes to the gateway question) but is not sure when she had the cold/flu, interviewers should record “Yes” to the gateway item, and DK to the dates of the cold/flu. Interviewers may probe for the season or time of year that the mom had the cold/flu to help mom recall the details. When mothers cannot recall particular dates, interviewers can record a wide time period using general dates such as months B3 to B1 (based on mother’s response), and then specify the number of days or weeks such as “1 week” during which the cold/flu occurred.

When the mother’s recall is poor, use the Comment button to describe the content of the mother’s actual response about whether and when she had a cold/flu.

**B38** Read the entire **list of symptoms** for each episode of a cold or flu, and record one response for each symptom. Although not an exhaustive list, these are the only symptoms of interest to the researchers. Do not probe for additional symptoms. CATI requires a “Yes” to at least one symptom.

**B38d-B40** These questions relate to **fevers accompanying colds or flu**. **B38d** asks for the subject’s perception about having a fever. The follow-up questions determine the length of the fever (specify the number of hours, days, weeks, or months) and if the fever was confirmed with a thermometer. Specify the highest temperature recorded in degrees Centigrade or Fahrenheit. (Record fevers in decimals from 98.6 F to 107.0 F or from 32.0 C to 41.9 C.)

**B41** If Mom did not take any medicine for this episode, the skip moves to the next cold/flu episode or, if there was not another episode, to **B47**.

**B42** Again, record **prescription and over-the-counter (OTC) drugs and herbal remedies**. Anything Mom reports is acceptable. If Mom reports having taken high doses of vitamins for this question, this is considered an acute usage, distinct from the Vitamins/Supplements section of the questionnaire. Therefore, record short-term high-dose vitamin use in **B42**. The Drug Dictionary is available as a pull-down menu. Read the short list of common medicines as a prompt if the subject cannot recall what she took. If the subject reports many medicines, CATI provides a scroll bar to move through the list.

Remember the rules for deleting and changing responses. If Mom changes her mind and says she took Sudafed, not Dristan, use the “delete” key to erase information and the “TAB” key to enter the corrected information. (See instructions in Section II B Completing Responses.)

**B43-B45** Record the start and end dates and frequencies of use for each medication listed in B42. If the subject cannot remember the month or day she stopped taking the medication, tab through the “stop” date field and record the number of (days, weeks, months) the medicine was taken. If she can’t remember the start date, you’ll need to fill that with DKs or CATI will think the start date was missing. If she can’t recall the date she

stopped the medication **or** the duration, select DK in the month and year of the “stop” date and CATI will skip over the duration.

**B46** Record the number of times the medicine was taken per (day, week, month, year). The skip proceeds to the next cold/flu episode or, if there is not another episode, to **B47**.

If the frequency of use does not fit the coding arrangement, there are some special options available at the end of the drop down list:

IV continuous

IV pump

Patch

Schedule varied/only as needed

Interviewers should use the option “schedule varied, used only as needed” in the response menu only when the mother really does not know or cannot recall, and cannot or will not be more specific even after probing. Interviewers should **probe** deeply to obtain the details about when (time frame) and how often (frequency and duration) the medicine was taken, and record details whenever possible. The Comments Button may also be used to record the details of what the mother said especially when the interviewer is not certain how to record/code the mother’s response. For example, if the mother says she had occasional headaches for which she took some type of painkiller, the interviewer should probe to determine the time frame and how often the headaches occurred.

### **Maternal Health--Infections**

**B47** This question asks about the Pregnancy Calendar time period (from –3 month to DOIB/DOPT). Read both illness options and record a response for each. The first illness includes **kidney, bladder, or urinary tract infection** (UTI). The second illness refers to **pelvic inflammatory disease** or PID.

**B48-B58** Ask this series of questions for each YES to kidney/bladder/urinary tract infection or PID in B47.

**B50-B58** Instructions for this series of questions about fevers and medications follow the same pattern as instructions for **B39-B46** above.

### **Maternal Health--Other Fevers**

**B59** This question asks about the Pregnancy Calendar time period (from –3 month to DOIB/DOPT). We want to capture information about all **fevers** that the subject has not mentioned previously. (You asked about fevers in previous questions about seizures, colds and flu, bladder/kidney/urinary tract infections, and PID. The Subject may have said NO to fevers for all those illnesses, so you may not have talked about any fevers previously.)

**B60** The fevers can be from any source, including bronchitis, pneumonia, an infection, or any other illness. Record each episode of fever even if the cause is not known. (After the interviews, coders will use the ICD-9-CM Coding System to code the illnesses.)



**B61-B70** Ask this series of questions for each episode of fever from B60. These fever and medication questions follow the same pattern as those about colds/flu and bladder/PID infections, except this series adds the question “Did you have a rash with this fever?” (**B64**). See instructions for **B39-B46** (colds and flu).

## **Maternal Health--Other Diseases**

**B71** Notice the time period (from –3 month to DOIB/DOPT). We want to capture information about all **other diseases** and illnesses that the subject has not mentioned previously.

**B72** “What did you have?” Then prompt the subject for additional illnesses by asking “Did you have anything else?” until the subject responds “No.” (CATI provides an “Anything else?” prompt.) Record each disease, illness, or condition that the subject mentions. Include chronic diseases, infectious diseases, sexually transmitted diseases, and any other illnesses that the subject mentions.

Do not list diseases, illnesses, or fevers that already were recorded in previous questions about diabetes, high blood pressure, colds/flu, infections, other fevers, injuries, etc. If the subject reports a long list of illnesses, use the scroll bar.

Probe so that the subject is specific about the type of illness so that it can be coded accurately later. (After the interviews, coders will use the ICD-9-CM Coding System to code the illnesses.)

For example, if someone gives a vague answer like “cancer” or “a tumor,” you should ask the subject to specify the type and/or site of the body where the cancer began. We are looking for terms like leukemia, lymphoma, breast or cervical cancer. If the word tumor is used, ask whether it was malignant or benign. (Cancer or tumors should be rare among this age group.)

**STDs:** List **genital herpes** and **HPV** (human papilloma virus or genital warts) in **B72** even if outbreaks occurred before (-3) but not during (-3) to (DOIB); however, select only the months of outbreaks in **B73**. Because these are viruses that you retain once you have them, outbreaks of lesions are important to identify. Whether or not there was an outbreak, ask **B74** and record medications for genital herpes because the medicine can be taken preventatively. **Gonorrhea (clap), syphilis, and chlamydia** are usually cured with antibiotics (unless a respondent continues to be sexually active with an untreated partner).

**B73** Select all months or time periods during which the subject had the particular illness. Notice that some of the months 4-6 and 7+ are grouped. It is not necessary to distinguish these months. However, in items **B74-B79**, you will ask about the medication details for specific months within the grouped months. (See example CATI screens.)

**B73-B79** Repeat the series of questions for each disease listed in B72. This series omits questions about fevers because all illnesses with fevers should have been mentioned in previous questions.

**B75** Under medications and treatments, you may record a course of **chemotherapy** as one treatment. Chemotherapy may consist of a series of treatments over a period of a few weeks to more than a year. People are usually not given more than two different regimens of chemotherapy.

Some people may mention here they've had **radiation treatments** or "x-ray treatments." We are looking for treatments here as opposed to diagnostic x-rays (which are covered in B99 and prenatal tests). Courses of radiation treatment may last from a few days to a few months. Usually a person would not receive more than two series of treatments. Record "radiation" in the field for medications or remedies and proceed as you would with medication details.

**B76-B78** If the subject cannot remember the month or day she stopped taking the medication, tab through the "stop" date field and record the number of (days, weeks, months) the medicine was taken. If she can't remember the start date, you'll need to fill that with DKs or CATI will think the start date was missing. If she can't recall the date she stopped the medication **or** the duration, select DK in the month and year of the "stop" date and CATI will skip over the duration.

These medication details do not need to be linked to the particular illness(es). Therefore, the CATI does not prompt the interviewer to specify the particular illness(es) in these medication questions.

**B79** If the frequency of use does not fit the coding arrangement, there are some special options available at the end of the drop down list:

- IV continuous
- IV pump
- Patch
- Schedule varied/only as needed

Interviewers should use the option "schedule varied, used only as needed" in the response menu only when the mother really does not know or cannot recall, and cannot or will not be more specific even after probing. Interviewers should **probe** deeply to obtain the details about when (time frame) and how often (frequency and duration) the medicine was taken, and record details whenever possible. The Comments Button may also be used to record the details of what the mother said especially when the interviewer is not certain how to record/code the mother's response. For example, if the mother says she had occasional headaches for which she took some type of painkiller, the interviewer should probe to determine the time frame and how often the headaches occurred.

## Maternal Health--Injuries

- B80** Notice the time period (from –3 month to DOIB/DOPT). We will accept whatever the subject considers an **injury** to be, including a car accident, fall, or being hurt by another person.
- B81** Record each injury or incident separately. List whatever the subject reports, from a cut finger to a car accident. You may probe by saying, “Briefly tell me what happened,” and by asking “Anything else?”
- B82-B88** Repeat this series of questions for each injury listed in B81. Record the date of each injury in **B82**. The medication questions (**B83-B88**) follow the same pattern as other illnesses (B74-B79). Also see instructions about time period and medications for **B29-B30** above.
- B82** Record the date that the injury occurred as month, day, and year.

## Maternal Health--Other Surgery

- B89-B94** This question asks about the Pregnancy Calendar time period (from –3 month to DOIB/DOPT). We will accept whatever the subject considers a **surgical procedure** to be, with the following exceptions:
- Interviewers should count **C-sections** and **abortions** as surgical procedures for births other than NOIB that occurred during the 3-month time period before NOIB’s conception. (The CATI sometimes denotes these months as B3, B2, and B1.) If NOIB was born as a C-section or abortion, then these procedures do **not** count as a surgery and we do not collect information on medications for the C-section or abortion with NOIB. However, medications would be recorded for any delivery procedure prior to the delivery of NOIB (for other babies) within this timeframe.
- Record the surgical procedure. If the subject cannot give the name of a procedure, get as succinct a description as possible for coding later. For example, if the mom had a breast implant procedure, specify the type of breast implant such as silicon, water, or saline, or specific other type.
- B91-B92** Ask these questions for each procedure in B90. Record separate responses for general and local anesthesia. Record each month or time period (e.g., B3 to T3) that the procedure took place.
- B93-B94** For each procedure, ask if the subject took any medicine or received any injections (**B93**), and record all medicines and injections in **B94**.
- B95-B98** Repeat this series of questions for each medicine in B94. Record the start and end dates and frequencies of use for each medication. If the subject cannot remember the “stop” month and day, tab through the “stop” date field and then ask the alternate question “How long did you take it?” and record the number of days, weeks or months. If she can’t recall the date she stopped or the duration, you may select DK in the month and year of the “stop” date and CATI will skip over the duration.

If the frequency of use does not fit the coding arrangement, there are some special options available at the end of the drop down list:

- IV continuous
- IV pump
- Patch
- Schedule varied/only as needed

Interviewers should use the option “schedule varied, used only as needed” in the response menu only when the mother really does not know or cannot recall, and cannot or will not be more specific even after probing. Interviewers should **probe** deeply to obtain the details about when (time frame) and how often (frequency and duration) the medicine was taken, and record details whenever possible. The Comments Button may also be used to record the details of what the mother said especially when the interviewer is not certain how to record/code the mother’s response. For example, if the mother says she had occasional headaches for which she took some type of painkiller, the interviewer should probe to determine the time frame and how often the headaches occurred.

### **Maternal Health—X-ray or Scans**

**B99-B104** These questions elicit the types of **x-rays and scans** that subjects had during the time period from –3 month to DOIB/DOPT. Notice these tests should not be related to the pregnancy (because pregnancy tests will be asked later). Repeat the series for each type and incident of the tests. After completing the series for the first test, CATI will automatically prompt the interviewer to ask if the subject had another test. If yes, CATI creates a new series of questions for the next text.

**X-Rays:** Interviewers should clarify to the subject that the question asks for the number of episodes or days or visits that the mother made to get x-rays, (e.g., NOT the number of x-rays or films a dentist or technician took each time).

CATI also provides the buttons “Add Xray/Scan” and “Next Xray/Scan” to facilitate moving among tests.

**B100** Ask, “Did you have any of the following...” and read the list “x-ray, CT/CAT scan, MRI (magnetic resonance imaging), radionuclide study or scan, or other x-ray or scan.” (If other, specify the type reported by the subject in the space provided.)

**B101** For each kind of test, record the body site from the alphabetical list in **B101** (such as abdomen, brain, and dental/teeth).

**B102-B103** Record all of the months during which a test was done (**B102**). Then ask **B103** for each month that the test was done, and record the number of tests the subject had (in the particular month).

**B104** Ask **B104** for all tests. If the same type of test was conducted during different months and the subject’s pelvis was shielded in one month but not the other, record the information in “Comments”.

## Maternal Health--Medication

### B105

**General List of Medicines:** The medicines in this drug list are of particular interest to the investigators (for time period –3 month to DOIB/DOPT). Many subjects will respond YES to one or more of them. Read the entire list and, when the subject responds YES, double-click the medicine to select it. Alternatively, you may highlight the medicine and click the large arrow to select it. The medicines are grouped by type. See the list below of brand and generic names. Practice the pronunciations of all these names.

The following medications are generic (the brands appear in parentheses):

Acetaminophen (Tylenol, Datril);  
Ibuprofen (Advil, Motrin, Nuprin);  
Aspirin,  
Amoxicillin,  
Valproic acid,  
Phenytoin (Dilantin),  
Methotrexate,  
Misoprostol (Cytotec),  
Nicotine patch NOS, and nicotine gum NOS

Currently, generic names do not appear for all of the brand name drugs on the list; e.g., Aleve is a brand name of naproxen sodium; Wellbutrin and Zyban are brand names of bupropion.

Interviewers should not provide descriptions of what the medications are, e.g., when reading the laundry list of medicines. Although the manual provides a glossary of medicines, interviewers do not need to explain the medicines. If the mother does not know what the medicine is or asks, “what is this”, the interviewer should state: “I don’t have any further information about these drugs/medicines.”

If the mother does not remember the name of the medicine or know what it is, then do not record that she used it. However, interviewers should record a comment stating what the mother said. If a mother responds “Yes” that she took a certain medicine but the mother misclassifies it (e.g., mistakenly calling it a vitamin), the interviewer should record “Yes” to taking that medicine but also should record a comment stating the mother called it a vitamin.

Be aware that mothers may report taking several medicines such as Tylenol, Advil, ibuprofen and acetaminophen, but not all of them during a certain time period; they may know which ones they used but can’t recall the time periods that they used the particular ones, and may use the names interchangeably. Use the Comment button to describe the mother’s actual response.

### B105ee

This “catchall” question (**B105ee**) captures any and all other medications, remedies, or treatments that the subject has not mentioned yet. Include medicines for asthma, allergies, STDs, HIV/AIDS, or other illnesses and conditions, if not previously mentioned. A Measles, Mumps, Rubella (MMR) immunization is one example that would fit here. Remember, if you spell an “other medicine” phonetically, to write “(ph)” after your attempt.

- B105, B105ee** If Subject responds “No” or “DK” to all B105 items including B105ee, skip to B110 (asking about herbal remedies).
- B106-B109** Ask this series of questions for each YES response listed in B105 and B105ee.
- B106** Start Dates: When a mother reports an actual start date for a medication that precedes the start date on the reference calendar calculated by the CATI, then the interviewer should record the first date of the reference period on the calendar (NOT the actual start date).
- CATI provides an alternate question for **B106** when subjects reported a medicine earlier in the interview: “Between –3 and DOIB, at what other times besides (DATE TO DATE) did you use (medicine)?”
- B106-B107** For both the start dates (**B106**) and end dates (**B107**) of taking a medicine, interviewers should obtain the month(s), day(s) and year(s) between –3 and DOIB (best guess [“BG”], if necessary). Use the “Comments” button if the answer is too complex to fit the coding scheme.
- B106-B108** Record the start and end dates and frequencies of use for each medication listed. If the subject cannot remember the month or day she stopped taking the medication, tab through the “stop” date field and record the **duration (B108)**, i.e., how long or the number of (days, weeks, months) the medicine was taken. If she can’t remember the start date, you’ll need to fill that with DKs or CATI will think the start date was missing. If she can’t recall the date she stopped the medication **or** the duration, select DK in the month and year of the “stop” date and CATI will skip over the duration.
- With medicines that are taken as needed, not necessarily regularly, you may get an answer like “Oh, about every couple of months, but I have no idea which months.” If this happens, **select the first month of her calendar and then select every other time period (e.g., B3, B1, P2, P4, P6, P8)**. Write a note under the “Comments” button to say that she could only estimate “every other month, not sure which ones.”
- B109** This question (**B109**) elicits an average **frequency** for the month or months the medicine was taken. If Mom asks what we mean by “times,” say that we want to know how often (e.g.: 3 times per day, or 6 times per month, or 2 times per week), regardless of the quantity taken at each time. The dose or quantity each time may be one tablet, two pills, one tablespoon, etc.
- If the pattern does not fit the coding arrangement, there are some special options available at the end of the drop down list:
- IV continuous
  - IV pump
  - Patch
  - Schedule varied/only as needed
- Use the “Comments” button to document details if a medication is administered intravenously (continuous drip), by medication patch, or by short-duration IV. For short-duration IV, also document the number of doses per day, week, or month.
- Interviewers should use the option “schedule varied, used only as needed” in the

response menu only when the mother really does not know or cannot recall, and cannot or will not be more specific even after probing. Interviewers should **probe** deeply to obtain the details about when (time frame) and how often (frequency and duration) the medicine was taken, and record details whenever possible. The Comments Button may also be used to record the details of what the mother said especially when the interviewer is not certain how to record/code the mother's response. For example, if the mother says she had occasional headaches for which she took some type of painkiller, the interviewer should probe to determine the time frame and how often the headaches occurred.

If the frequency the medicine was taken is significantly different in one month compared to another month, you may use one subrecord to record the frequency in one month and a second subrecord to record the different frequency in the other month.

The frequencies of OTC medications can be more difficult to pin down. If she varied her use, ask "How often did you take it on average?" If she says she cannot remember, ask, "How often do you think you took it?" or if she's really having a hard time, "When you take (medicine), how do you usually take it?" You may use the "Comments" button if the pattern does not fit the coding arrangement.

### **Herbal or Folk Medications (NEW ITEMS):**

**B110** This "gateway question" (**B110**) elicits information specifically about **herbal or folk remedies or medicines** that may be used for any reason, including to treat medical conditions, to lose weight, to prevent disease, or to maintain or promote health. The investigators are primarily interested in oral or injected remedies that are used internally (e.g., not in topical ointments or creams for the skin). The time period is -3 through DOIB. Record Yes or No.

**B111-B114** If Yes to B110, specify each herb or folk medicine. Then, for each remedy, ask the series of questions **B111 through B114** to obtain details about the start date, end date, duration (how long), and frequency (how often).

Follow the same instructions from series B106-B109 above as guidelines to probe and document the details about each of the herbs and folk medicines mentioned. The time period is -3 through DOIB.

Since the gateway question asks about herbal remedies for any purpose and not necessarily related to an illness or condition, interviewers may substitute the word "reason" for "illness" in the detail questions about herbs and folk remedies (Series B106-B109). For example, "When did you start taking [herb] for this reason?"

Again, as with OTC medications, the frequencies of herbal and folk remedies may be difficult to pin down. If Subject varied her use, ask "How often did you take it on average?" If she says she cannot remember, ask, "How often do you think you took it?" or if she's really having a hard time, "When you take (remedy), how do you usually take it?" You may use the "Comments" button if the pattern does not fit the coding arrangement.

## **SECTION C: PREGNANCY HISTORY AND FERTILITY**

### **General Instructions About Pregnancy History**

- Be sure to read the transition statement about pregnancy experiences.
- For definitions of the procedures asked about throughout Section C, see the Glossary of Terms.

### **Specifications for Questions About Pregnancy History**

#### **Pregnancy History and Fertility**

- C1** Read the script slowly enough to make sure that all the outcomes are heard. The number of pregnancies includes live births and all other outcomes. The time period includes all pregnancies before the index baby (NOIB). This is not a lifetime total; do not include NOIB or subsequent pregnancies.
- C2-C4** CATI will create separate records for each pregnancy, and will prompt you to ask about each pregnancy in sequential order.
- C2** **C2** refers to the sequential number of the pregnancy. It ascertains multiple births (e.g., twins).
- C3** **C3** ascertains the outcome for each pregnancy (and each baby in a multiple pregnancy). Read the list of outcomes.
- C4** This item determines the date of the birth (“end date”) for the pregnancy immediately before the index baby (NOIB). Record month, day, and year.

#### **Pregnancy History for Index Baby (NOIB)**

- C5** Notice the lead-in script indicating that the next questions are specific to the pregnancy with NOIB. Select “lbs” (pounds) or “kgs” (kilograms) to specify the subject’s weight before her pregnancy.
- Round up half pounds (kilograms) of weight. If Mom gives you a range of weights, like 120-125 pounds, ask “Which would you say...”. Ask for her “best guess.”
- C6** Select number of pounds (“lbs”) or kilograms (“kgs”). Round up half pounds/kilograms. Select whether gained, lost, or no change.
- If Mom says she gained some, then lost some, ask “How much did you gain overall?” If an unusual pattern warrants a note, write one. This is one of those issues where you must be careful not to appear judgmental. Lots of moms will exclaim that they gained a lot of weight. Some will seem embarrassed. You should respond in an understanding and neutral way, but you can just give a cheerful “Okay” or “I see.”
- C7** Round up half inches of height. Record both feet and inches. If 5 feet, record 5 feet and 0 inches. If Subject gives answer using the metric system, make a “Comment” to



specify her response (e.g., in meters and centimeters).

- C8** Round less-than-half a week down and half a week or more, up. You may record either the number of weeks or months.

**Date or Months:** Questions like this are repeated throughout the questionnaire. We are giving Mom a choice. If she does not remember the date, which could be a month, unknown day and year, then she may remember the number of weeks she was pregnant. Either will do.

#### **Contraceptive Use:**

- C9** If Mom says NO to a “big” gateway question like this one, which is followed by a skip over a large section, briefly confirm, “You didn’t use any pills or mechanical or chemical methods of birth control during that year?” before moving on.

- C10-C12** These questions elicit **oral contraceptive** use. If Mom does not know the name of her pills, read the list at the right-hand side of the question, and double-click each OC used. (Do not read the menu list under the response space.) Whatever name she gives, whether on the list or not, record it in the space provided. Spell it phonetically if necessary and put a “(ph)” next to your attempt. CATI creates room for multiple OCs.

CATI will prompt you to ask the month(s) of use from –3 to 7+ (in **C12**) for each OC. You may select the YES months, and then use the “Fill Rest with No” button. Use the Exit Door (“Close Form”) button to close this series.

The word “pills” was added after “birth control” in the question “did you use any birth control or morning after pills” because mothers sometimes confused its meaning with birth control measures in general.

- C13-C15** These questions elicit information about any **other kind of contraception** used. Select from the menu of methods provided, including condoms (distinguish male and female condoms), diaphragm, sponge, spermicide NOS, rhythm, etc. If “Other, specify” method, select “other” and then record what it is in the “specify” field. (For example, “vaginal film” would be specified under “other” to distinguish it from female condoms, foam, or other methods.)

- C16** Read these responses and select one response. To further clarify, a) implies that you planned to get pregnant; b), that you temporarily did not use your birth control for whatever reason; and c), that your birth control method failed.

See also notes under Fertility Section C18 about awkward skip patterns related to this item.

- C17** Select one response to indicate whether or not subject wanted to become pregnant then, later, not at all, or did not care.

Some mothers have difficulty and may feel guilty answering these questions or choosing among the options “Wanted to become pregnant then” and “Wanted to wait

until later”. Sometimes these items may be awkward to ask and sometimes don’t seem appropriate given earlier responses by mothers. The questions, however, come from a study of pregnancy intendedness and have been determined to be the most reliable for ascertaining the information the investigators are looking for. Thus, changes cannot be made in these items.

See also notes under Fertility Section C18 about awkward skip patterns related to these items.

## **Fertility Details**

### **C18, C18a**

This is a “gateway question” to all the fertility drugs and procedures for both parents. A “NO” here means neither parent had any fertility assistance, either with medication or procedures, for the index pregnancy. If the mother had reported earlier not knowing whom the father was, alternate wording will appear that just asks about the mother (C18A). A NO or DK response will skip to C35.

Use the “Add”, “Next”, and “Previous” buttons to navigate among multiple medicines and procedures. CATI will prompt, asking if there are additional medicines or procedures.

**Awkward Skips:** Interviewers have mentioned **awkwardness of certain skip patterns after asking C17**, “At the time you became pregnant, did you want to be pregnant then, did you want to wait until later, or did you not want to be pregnant at all...”. If the second or third response option is chosen, the next question **C18** on Fertility Details screen seems inappropriate, i.e., “Did you or FOIB take any medications or have any procedures to help you become pregnant?” Paula Yoon clarified that the reason we must ask these questions, even when it seems inappropriate, is that subjects sometimes report fertility and contraception behavior that is inconsistent with earlier responses or attitudes. For example, although the mother may not have wanted to become pregnant, she or the father may still have had fertility procedures because the father wanted a child.

The fertility gateway item can become particularly awkward when the subject has said there was an accidental interruption in birth control (e.g., in C16). Paula Yoon approved a “clarifying or minimizing statement” to say something like “This situation may not apply to you, ...” before the C18 gateway fertility item when the mom has felt embarrassed about accidental lapses in contraception. Thus, interviewers may use a “prompt” regarding pregnancy intendedness and contraceptive use when the mom seems embarrassed about an accidental interruption in birth control. (The issue concerns transitions from the items about birth control beginning with C8, contraception use in C16, pregnancy intendedness in C17, and fertility procedures gateway C18.) In situations when the mother told an interviewer that there was an accidental lapse in birth control and then responded in C17 that she did not want to become pregnant then or wanted to wait until later to be pregnant, then interviewers may add the following **probe** before Fertility Gateway item C18: **“This situation may not apply to you, but...” “Did you or FOIB have take any medications or have any procedures to help you become pregnant?”**

Refer to the following infertility primer to help familiarize yourself with the terminology and procedures.

## **INFERTILITY PROCEDURES PRIMER--**

### **Information for Interviewers:**

Attachment B contains an **Infertility Primer**, a summary of infertility procedure information. It is interviewers as background information only. **Do not provide this fertility procedure information to the mothers.** It is too complicated to try to explain all of the different fertility information to the mothers. If a mother used any of these to get pregnant, she will most likely know what they are. If she is confused about the terminology, ask her to answer the questions as best she can and record her response in a comment field. If Subject asks you, the interviewer, to explain the procedures, **tell her you do not have information available to you to explain these procedures, but that you will record any information she is able to give you about the procedures she used.**

### **Fertility Details--Father**

**C19-C21** The first questions cover any medications the father may have taken to help her become pregnant. For example, he may have been given an antibiotic to clear up an infection affecting his reproductive capabilities.

**C23** If the Dad had any procedures, type the Mom's response into the text box. Some of Dad's procedures are sperm analysis, reanastomosis of the vas deferens, and varicocele removal. Practice the pronunciation of the terms while in training.

**NOTE:** Although the current CATI does not provide a menu for fathers' procedures, a menu list may be developed in the future.

Accept information pertaining to any pregnancy, not just the index pregnancy. The date of the procedure will tell us whether it related to NOIB.

For every YES response to C19 or C22, record the medicine/procedure in the space provided. Then ask the dates (**C21** or **C24**) for each medicine/procedure before asking about the next.

### **Fertility Details--Mother**

**C25-C35** These questions cover any fertility drugs (**C28-C30**) and procedures (**C25-C27, C31-C35**) questions for the mother. Use the "Add", "Next", and "Previous" buttons to navigate among multiple medicines and procedures. CATI will prompt, asking if there are additional medicines or procedures.

**C26** Select the name of the procedure from the list. If "other", specify the type. CATI will prompt you to ask if there were additional procedures.

**C28** If subject cannot recall, read the medicines on the "short list". She may have taken more than one drug and the dates taken (**C30**) may overlap. You may record in vitro medications either in this section or in the Pregnancy Complications Prevention section below; either place is okay.

- C30** The dates may include dates for a drug taken after conception occurred. Usually, in this event, Mom did not know she had become pregnant and was continuing the drug.
- C31-C32** **C31** is a catchall question to capture other fertility procedures. In **C32**, use the menu to select all other procedures received 2 months before the NOIB pregnancy. CATI will prompt for additional procedures.
- C33** Mom may be accustomed to the term “times” instead of “cycles.”
- C34A-C34B** Donor and frozen cells may not be used at all in some of the procedures. Verbally, the questions will sound like two lists. Select a response code for each of the 6 items.
- Donor sperm and eggs are from someone other than the mother and father of the pregnancy. Thus, if the sperm and/or egg(s) are from Mom and Dad, they are not donor cells. Sometimes the father's sperm can be mixed with a donor's. In this case, the response for donor sperm would be YES. The definition of a donor embryo is one for which both the egg and sperm were contributed by donors.

#### **Complications Prevention Medications:**

- C35 Series** This new series of items has been added to prompt mothers to recall **medications taken to prevent pregnancy complications or pregnancy loss** during the pregnancy with NOIB. While the above fertility items asked about medicines taken in order to become pregnant, this item prompts subjects to mention medications taken after implantation.
- In Vitro Medications:** Interviewers may accept and record medications taken when in vitro that a mother mentions in the fertility section, before the Complications Prevention items. Alternatively, in vitro medications can be recorded with Complications Prevention medications. Either place is okay.
- C35A** This gateway question asks if the subject took any medicines including hormones, steroids, or injections. Some Rh-negative mothers may have received Rhogam injections during their pregnancy.
- C35B** Record all medications that subject reports, and use the list to probe if needed.
- C35C-C35F** Record the details for each medication.

#### **Morning Sickness**

- C36-C47** This series asks about **morning sickness or nausea** during the pregnancy with NOIB.
- When a mother responds “Yes” that she did experience nausea or vomiting but then volunteers that she **never** had one of the conditions (either nausea or vomiting), interviewers do not need to keep asking how often she had that condition for each time period. Instead, interviewers may select the option “Never” for each time

period without repeating the question for each month. For example, if Mother answers YES she had nausea or vomiting but volunteers she never vomited, then the interviewer may select Never for all time periods without re-asking how often Mother had vomiting, but interviewer should still ask how often Mother had nausea for each time period. Analyses will not need to distinguish between 2<sup>nd</sup> and 3<sup>rd</sup> trimesters, therefore interviewers do not need to record distinctions about “timing” of nausea/vomiting for these trimesters. Interviewers may make a comment to describe what the mother reported.

Vomiting is defined as anything that comes up, even if it’s not much.

- C37** Use the “Every Month” and “Fill Rest with No” buttons as needed.
- C38-C39** For each YES response to **C37**, substitute the applicable month or time period when asking questions **C38** and **C39** about how often the subject had nausea or vomiting. Also, read the response menus as part of these questions. If the subject’s response pattern is the same for each item, you may use the “Ditto Nausea/Vomiting” button to repeat responses.
- C40-C41** Notice that you will list all **medications and treatments** that the subject used. Record each separately in C41. (There is no “short list” of responses in the CATI for C41.)
- C42-C44** Record the start and end dates and frequencies of use for each medication listed. If the subject cannot remember the month or day she stopped taking the medication, tab through the “stop” date field and record the number of (days, weeks, months) the medicine was taken. If she can’t remember the start date, you’ll need to fill that with DKs or CATI will think the start date was missing. If she can’t recall the date she stopped the medication **or** the duration, select DK in the month and year of the “stop” date and CATI will skip over the duration.
- C45** This question elicits an average **frequency** for the month or months the medicine was taken. If Mom asks what we mean by “times,” say that we want to know how often (e.g.: 3 times per day, or 6 times per month, or 2 times per week), regardless of the quantity taken at each time. The dose or quantity each time may be one tablet, two pills, one tablespoon, etc.
- If the pattern does not fit the coding arrangement, there are some special options available at the end of the drop down list:
- IV continuous
  - IV pump
  - Patch
  - Schedule varied/only as needed
- C47** Select the number and specify “lbs” (pounds) or “kgs” (kilograms) of weight lost during the period of nausea or vomiting. Round up half pounds (kilograms) of weight. If Mom gives you a range of weights, like 5-10 pounds, ask “Which would you say...”. Ask for her “best guess.”
- If the mother lost weight but gained it back later during the pregnancy, record the lost weight and write a Comment that she gained it back. Write a Comment to describe any unusual patterns. Be careful not to appear judgmental. Moms may exclaim that they

lost weight, and some may seem embarrassed. You should respond in an understanding and neutral way, but you can just give a cheerful “Okay” or “I see.”

## **Prenatal Care**

**C48** This question begins a series of questions on diagnostic tests to look at fetal health during pregnancy. It asks the gateway question to determine if Mom had any prenatal care for NOIB.

**C49** The first priority is to obtain the actual full date of the first prenatal visit. Interviewers should **first probe** by asking for the date, but then can **probe**: “How many weeks or months?” The weeks are more important than months. The menu provides options such as Month P5 (5<sup>th</sup> month). A response of 5 ½ months would correspond with the P5 or 5-months option.

**Prenatal Medications and Other Date Screens:** In the future, CDC may add a place on the CATI screen to record the number of months so that interviewers and subjects will not have to calculate the conversion (current choices are 0-46 weeks, and T1, T2, T3). CDC may also add options for beginning, middle, and end of month on pull-down menus for the following screens: Prenatal Care and medicines, Ultrasounds, Blood Tests, Prenatal Tests-Amnio/CVS.

**C50** Currently, most women have at least one **ultrasound** test during pregnancy; however, the test is optional. This question asks only for ultrasounds that showed an abnormality.

**C51** The question gives Mom the choice of either a specific date or number of weeks of the first abnormal result from an ultrasound. Tab through the date if she gives the number of weeks.

**C52** Record all of the abnormalities that the mother reports. If there is not enough space in the response box, use the comments button to record additional details about the abnormality.

**C53-C55** This series ascertains results of other ultrasounds that identified different abnormalities. CATI will prompt you to repeat C53 and the series as necessary.

**C56-C74** **Prenatal Blood Tests and Medical Procedures:** Definitions developed at CDC for MSAFP, Fetal echocardiography, and other prenatal tests or medical procedures are listed here. In addition, the definitions for MSAFP, Amniocentesis and Chorionic Villus Sampling now appear on the CATI screens. Interviewers may use these to provide a brief description of the prenatal procedures to mothers if mothers ask for clarification.

### **Definitions that interviewers can use to explain procedure to mom if asked:**

MSAFP - Maternal serum alpha-fetoprotein or MSAFP is a blood test done early in pregnancy to determine if there is a higher-than-average risk of certain birth defects such as spina bifida and Down syndrome. Alpha-fetoprotein (AFP) is a substance produced by the liver of the fetus and a small amount of AFP passes into the mother's bloodstream. AFP levels can be measured during pregnancy by taking a sample of blood from the mother's arm.

Amnio – Amniocentesis is a procedure done during pregnancy to test for various birth defects. A thin needle is inserted through the abdomen and into the uterus and a few teaspoons of amniotic fluid are withdrawn. The fetal cells that float in the amniotic fluid are then studied in a lab.

Chorionic Villus Sampling - Chorionic villus sampling or CVS is a procedure done during pregnancy to test for various birth defects. A thin tube is inserted through the vagina and cervix and a small piece of the tissue from the pregnancy sac is removed. Sometimes the procedure is done by inserting a needle through the abdominal wall, similar to an amniocentesis. The cells from the tissue are then studied in a lab.

Fetal echocardiography - Fetal echocardiography or fetal echo is a type of ultrasound that allows a very detailed view of the four chambers of the heart. It is used to detect most forms of congenital heart diseases.

Fetal Dye Study – A dye may be injected into the amniotic sac to study rupture of the membranes or during an amniocentesis when there is more than one fetus.

**C56** When asking this question, say the full name of the procedure **Maternal Serum Alpha Fetoprotein**, then say “...or MSAFP.” Record a YES response if Mom says yes to one or more of the procedures (i.e., MSAFP, double screen, and triple screen). Refer to the definitions above.

For MSAFP, some women will reply, “I had one when they usually recommend it but I don’t remember when it was.” You may say, “The test is usually done at 16-18 weeks. Does that sound right?” If she agrees, write a note to say that her reply was “the recommended time.” The Coding Team will assign a special code to that reply. The “(16-18 WKS REC.)” prompt is to be used only under the above circumstance, when Mom said she did not know exactly when, but it was at the recommended time.

**C59** Read the MSAFP test-result response categories, and select one (i.e., normal, high, low, or abnormal/NS). “High” and “Low” are specific test results within the “Abnormal” result category. If the subject knows the specific result, select her response of high or low rather than abnormal. However, if the subject knows that her test results were abnormal, but does not know whether the result was high or low, then select “Abnormal/NS (nonspecific) as the response. (Some subjects know that their test was high or low, but do not know whether this was abnormal.)

If the mother reports that she had all of the blood tests but does not know if any of the tests was called an MSAFP, then the interviewer should select the “Don’t Know” response and record a comment that explains what the mother said. If the mother reports that she had an MSAFP, then interviewers should record a Yes responses even if it seems that the mother may be mistaken; again, record a comment that explains what the mother said. (Mother’s response should be recorded as she gives it.) Often the test is just called an AFP.

**C58, C61, C66,  
C72, C77**

These all allow Mom a choice, either to give the date or the number of weeks pregnant she was when the tests were done. Either will do.

<b>C60-C64</b>	This series asks about <b>Amniocentesis</b> or amnios. Refer to the definition above if the mother asks for clarification. Record the types of any abnormalities in <b>C63</b> . Refer to the definition above if the mother asks for clarification.
<b>ALL TESTS</b>	The CATI now accepts multiple test dates. A screen will appear after each date is entered asking if there are any more. A “yes” will bring up another set of date fields. Refer to the definition buttons on the screen if the mother asks for clarification. Record the types of any abnormalities in <b>C68</b> .
<b>C70-C74</b>	This series asks about prenatal diagnostic tests such as <b>fetal echocardiography</b> or <b>fetal dye studies</b> . Refer to the definition above if the mother asks for clarification. Record all abnormalities in <b>C74</b> .
<b>C75-C78</b>	This series asks about any other prenatal medical procedures such as <b>blood transfusions</b> or <b>fetal surgery</b> . Record the name of the procedure in <b>C76</b> , and the reason it was performed in <b>C78</b> .
<b>C79</b>	This question is asked of all moms who said YES to any prenatal diagnostic procedure at all, including ultrasound. If the respondent is unclear about the language "prenatal diagnosis procedure", clarify by stating "the tests we just talked about."
<b>C79-C84</b>	If YES to <u>any</u> complication (including a pelvic exam), write the names of each test or procedure in the spaces provided ( <b>C80</b> ). Read the symptoms and in <b>C81</b> , selecting a response for each. Add any other symptoms in the Specify field. Record any medicines taken in the spaces in <b>C84</b> . It is not necessary to link the medicines with symptoms.



## SECTION D: SUPPLEMENTS

### D1-D9

Notice that the time period for vitamins and minerals is -3 through DOIB. **D1** asks if Mom took any **prenatal vitamins**. Record the names for each, then ask about the frequency and duration details for each (**D1aa-D1ee**).

Prenatal vitamins are also multivitamins, but they are especially formulated for pregnancy. Physicians often prescribe them for pregnant women. A woman could decide to take some other multivitamin, or to continue one she had been taking instead of or in addition to prenatal vitamins. Some physicians do not recommend vitamins for women in good health with excellent nutritional habits.

Often, moms start taking prenatal vitamins when they discover they are pregnant. But sometimes a preparation may make them feel ill or constipated, so they switch to another preparation. Or they may occasionally forget. Start and stop dates for one supplement can be documented on the **D1bb-D1cc** calendar. If the subject cannot remember the month or day she stopped taking the vitamin, tab through the “stop” date field and record the number of (days, weeks, months) the vitamin was taken. If she can’t remember the start date, you’ll need to fill that with DKs or CATI will think the start date was missing. If she can’t recall the date she stopped the vitamin **or** the duration, select DK in the month and year of the “stop” date and CATI will skip over the duration.

Document whatever information the subject knows about the supplement. Probe by reading the short list of popular brand name prenats on the screen. If she doesn’t give you a brand name, ask if she remembers the brand name. Record brand name with the type of vitamin in D1aa. If Mom does not remember the name after probing, record a prenatal, NOS code from the Slone dictionary.

**Frequency and Duration:** Record the frequency and specify whether it is number of days, weeks, or months.

The duration of use questions can show short-term use, for example, if Mom took something for a couple of weeks and discontinued it. Regular daily use is represented as 30 days or 4 weeks. You may estimate two weeks as 14 days, and one month as four weeks or 30 days. However, if a respondent took the medication “almost every day” and specifies “28” or “29” days per month, then 28 or 29 are acceptable answers. Other response options include IV continuous, IV pump, patch (worn continuously), and schedule varied/used only as needed.

### D2

Notice that the time period is -3 through DOIB. Read the list of **single vitamins and minerals**, and record YES or NO for each. Then ask the same series of details from **D2aa-D2dd**. Notice that one exception here is the vitamin B complexes. They are included here because they are all forms of a B vitamin.

As an example, a mother may take calcium carbonate for awhile and then take calcium citrate with vitamin D, but the pull-down list under the details section does not allow you to replace “calcium” with the more specific types of calcium listed. (Thus the CATI does not record the unique code at that point.) Interviewers may use the “Comments” button to record specifically what the mother actually took. Interviewers also could record the specific information under the “other vitamins” item where the CATI can select the unique code.

**D3-D8** **D3 to D8** cover any **multivitamins or vitamin complexes**. This is where a Mom would report taking a combination of different vitamins in one pill. This may include multivitamins that include minerals. You may include comments to describe the components of the complex.

**D9** Finally, the last item in the series elicits any other vitamins, minerals, amino acids, antioxidants, etc. she might have taken. Whatever Mom reports is acceptable. Record the names for each, get brand names when possible, then ask about the dates, duration and frequency of use.

### Cereal and Food Supplements

**D10** Notice that the time period is -3 through DOIB. We want to know if Mom ate any **cereal** at some average frequency. Both cold and hot cereals apply. Include grits. If moms inquire as to why we ask about cereals, you may say that some cereals contain vitamins and that's what we're looking for here.

**D11** We are asking for the cereals they ate most often. List the names of each cereal, and include the brand name if she gives it. Probe for and record the **five cereals eaten most often**: "Which five did you eat the most

**D12** A regular frequency for the whole year will show YESes for all eight time periods. If Mom says she ate the cereal about every other month but she absolutely cannot say which ones exactly, then select YESes every other month starting with the -3 month, and both YESes for the T2 (4-6) and T3 (7-9) periods. Then write a note to say, "every other, not sure which."

**D13** Record the average number of servings she reports for each cereal. The CATI prompt tells her she may refer to the list of food frequency responses sent to her in the mail.

**D14-D17** Notice that the time period is -3 through DOIB. We want to know if Mom ate or drank any **food supplements**. There is a pull-down menu of types of food supplements. You may use these to probe if she needs help remembering names.

### Dietary Assessment

**D18a-D18ff** Ask Mom if she has (can get) the **List of Food Frequency Choices** that she received with her letter in the advance mailing.

Carefully read the CATI script for this series of questions to the subject. Read the response choices with the subject before reading the food items.

Read each food item, and also read the average serving size. If Mom does not have her list, you may need to repeat the choices to her for each food item until she gets the hang of it. Then record one response for each item before moving to the next food. For example, 1M means 1 serving per month, 1W means 1 serving per week, and 1D means 1 serving per day.

Interviewers should **not change the wording of any items**, but must read items as they appear in the survey. Since the food frequency items were developed as an index that has been validated in this form with these particular items, we cannot change the wording of the items.

Interviewers should **read the serving size** for consistency.

Interviewers should **not probe for details about the foods**, and should only record details if the mother reports a detail or volunteers the information. (For example, we cannot change the bread item to include hotdog buns and hamburger rolls. However, interviewers can tell a subject that bread includes buns or rolls only if the subject asks about it or volunteers the information.)

Interviewers should **not adjust the frequency to account for low fat items that the mother reports**. For example, if the mother reports eating low fat cheese, the interviewer should not lower the frequency, but should add a comment, if possible, that specifies the cheese was low fat.

Foods that subjects volunteer must be incorporated into the existing questions where they would fit best. Interviewers should make comments and alert supervisors when questions arise about specific foods. In turn, supervisors will alert the CDC coordinator about such issues. Comments should describe how the issue was coded or handled.

## **Food Clarifications**

Here are some decisions to help you know where to record some food items when the subject volunteer the information. The general idea is to be as inclusive as possible with the food items. This list should be used as a guideline.

**Skim or lowfat milk:** Record all 1%, 2%, and skim cow milk consumption here, whether the milk contains vitamins, Acidophilus, Lactaid, chocolate or cocoa. Include goat's milk. Use the comment button to record details such as acidophilus, goat's milk, etc. Do not include soy milk or rice milk.

**Whole Milk:** Record all higher fat cow milk consumption here, whether the milk contains vitamins, Acidophilus, Lactaid, chocolate or cocoa and whether it came straight from the cow. Include goat's milk. Use the comment button to record details such as acidophilus, goat's milk, etc. Do not include soy milk or rice milk.

**Soy Milk and Other Soy Products:** The interview does not ask about soy milk or other soy products such as tofu, Tofutti, etc., and there is no place to record these items in the CATI. Interviewers may use the Comment button to record these products if the subject volunteers that she uses them, but the soy products will not be part of the food frequency index.

**Yogurt:** Include dessert yogurt products, yogurt dips, and yogurt used in baking.

**Ice cream:** 1/2 cup equals 1 scoop of ice cream. Include ice milk, and use Comment button to specify it. Do not include sherbet, ices (made from water), rice dream, or tofutti (or tofu-product-frozen desserts) in the frequency, but interviewers may use the Comments button to record these products if the subject volunteers that

she eats them.

**Cottage or ricotta cheese:** Include cheese used in cooking (e.g., lasagna) if this is how participants use it. If they specify it is low fat cheese, use the comment field to record “low fat”.

**Other cheese e.g., American, cheddar, etc., plain or as part of a dish:** Include cheese dips, sauces, cheese spreads and cream cheese here.

**Margarine (pat), added to food or bread, exclude use in cooking:** Do not include margarine to grease a pan or in a recipe. Do not include shortenings such as Crisco here.

**Butter (pat), added to food or bread, exclude use in cooking:** Include salted, unsalted or whipped butters here. Do not include butter to grease a pan or in a recipe. Do not include shortenings such as Crisco here.

**Fresh apples or pears:** Include fresh apples or pears whether eaten raw or used in salads, cooking, or baking.

**Oranges:** Include fresh oranges, canned oranges, canned mandarin oranges, fresh or canned tangerines. Do not include grapefruit with oranges; instead record grapefruit with Other Fruits.

**Orange juice (small glass):** For reference, a small glass probably contains about 5-6 oz, but it is up to the respondent to judge this. Do not include grapefruit juice here.

**Peaches, apricots, plums, or nectarines:** Include raw peaches, apricots, plums, nectarines as well as fresh used in salads, cooking, or baking. Include fresh, frozen, or canned.

**Bananas:** Include fresh bananas, dried bananas, and those used in baking. Also include plantains here.

**Cantaloupe:** Include fresh cantaloupe as well as frozen cantaloupe or other melons (e.g., honeydew).

**Other fruits fresh, frozen, or canned:** Include other fruits whether eaten raw, frozen, or canned, or used in salads or baked in cooking. Include mixed fruits here (e.g., fruit cocktail). Include grapefruit here.

**Fruit equivalence:** 1 fresh fruit item can equal a ½ cup serving.

**Tomatoes or tomato juice:** Include tomatoes used in cooking and salads. A small glass could be 5-6 oz, but use the respondent’s judgement.

**String beans:** Include fresh, frozen and canned string beans.

**Broccoli:** Include fresh or frozen.

**Cabbage, cauliflower, or brussel sprouts:** Include fresh or frozen.

**Carrots, raw (1/2 carrot or 2-4 sticks):** For baby carrots, use 2 per 1/2 carrot.

**Carrots, cooked:** This also refers to steamed carrots.

**Peas or lima beans:** Include sugar peas, snap peas and butter beans.

**Spinach or collard greens, cooked:** Include raw spinach (e.g., serving of spinach salad).

**Refried beans:** Any type of bean prepared as refried beans should get recorded here (e.g., black, pinto, kidney).

**Beans or lentils, baked or dried:** This refers to cooked, frozen, and canned beans. It includes baked beans. Dried beans refers to beans that have been cooked, but were dry before cooking.

**Yellow (winter) squash:** Include butternut, acorn, crookneck yellow, and zucchini. You do not need to record a comment describing what type of squash was eaten.

**Raw chile peppers, jalopeno:** Include other raw peppers, e.g., habanero peppers. Include dried, canned, or pickled peppers.

**Salsa (1 cup):** Include tomato and fruit salsas (any type of salsa).

**Eggs:** Includes any style of preparation (e.g., raw, fried, boiled, poached, scrambled, etc.). Do not include eggs used in baking (e.g., in a cake).

**Chicken or Turkey (4-6 oz.):** Include chicken or turkey used in a main dish or in a mixed dish. (Notice the serving size of the poultry.)

**Bacon:** Include any type of meat or poultry bacon, e.g., pork, turkey bacon. Do not include soy, tofu, or vegetable/grain-based “bacon”.

**Hot dogs:** Include any type of meat or poultry hotdogs (e.g., beef, pork, chicken, and turkey hot dogs). Do not include soy, tofu, or vegetable, or grain hot dogs.

**Processed Meats, e.g., sausage, salami, bologna, chorizo, etc.:** Include any type of meat or poultry, e.g., beef, pork, turkey or chicken processed meats, such as turkey sausage. Do not include soy, tofu, or vegetable products.

**Organ Meats, Barbacoa, Menudo, tongue, intestines:** Do not include natural casings on sausage as a type of intestines here. (All types of sausage should be counted with Processed Meats.)

**Hamburger (1 patty):** Size of the patty does not matter. It can be ¼ to ½ pound. Include any type of meat, e.g., beef, pork, turkey, chicken. Do not include soy, tofu, rice, grain, or veggie burgers.

**Beef, Pork, lamb, or cabrito as a sandwich or mixed dish, e.g., stew, casserole,**

**lasagna, etc.:** If the mixed dish is also the main dish, then count the meat as a mixed dish. But most importantly, only count this meat once (i.e., not also with meat as a main dish).

**Fish:** Include canned tuna and fish sticks, but you need not specify this. Do not include shellfish (e.g., shrimp, oysters, clams, scallops, crabs, or lobster) here or elsewhere in the assessment, but do record the information under a Comments button.

**Chocolate (1 oz):** Include any type of chocolate, e.g., dark or milk chocolate. Include chocolate candy alone or as part of a “mixed” candy (e.g., with a chocolate coating or filling). Do not include chocolate cake, cookies, or pie here; they should be recorded with those types of items instead.

**Cookies:** Subject and interviewer use judgement about size. Very large deli cookies should count as 2 or 3. Include chocolate chip and chocolate cookies here, and cookies with nuts.

**Pie:** Include any size slice of pie. Include chocolate pie and nut pies (e.g., pecan) here.

**Cake:** Include any size slice of cake. Include chocolate cake, and cake with nuts.

**Bagels, Hot Dog Buns, Hamburger Buns:** Include with white bread (or dark breads if the mother specifies dark). You do not need to make a comment to specify if it is bread, pita, bagel, bun, roll, muffin, etc.

**Potatoes baked, boiled (1), or mashed (1 cup):** Include raw potatoes and steamed potatoes. Include potatoes as part of a dish if the potatoes are a substantial part of the dish, e.g. shepherds pie.

**Tortilla:** Refers to any size tortilla. Include either corn or wheat flour tortillas.

**Potato Chips or Corn Chips:** Include either fried or baked, fat-free, or those made with Olestra (fat substitutes).

**Nuts:** Include nuts used as part of a dish.

**Peanut butter:** Include other nut butters such as cashew, almond. Do not include seeds or seed butters such as sesame or tahini here or elsewhere in the assessment; but do record the information under Comments button.

**Oil and vinegar dressing:** Include vinaigrette and non-creamy Italian. Do not include creamy dressings or mayonnaise. Do not record responses for other salad dressings or condiments with the dietary assessment, but record under Comments.

## Food Pronunciations and Definitions:

- **Barbacoa** (bahr bah co' uh): an organ meat
- **Cabrito** (cah bree' to): baby goat meat
- **Chorizo** (cho ree' zo): highly seasoned pork sausage
- **Menudo** (meh noo' do): an organ meat, entrails

## Caffeine

**D19-D28** Be careful to read the lead-in script; it tells the mother what the time frame will be, i.e., before she became pregnant with NOIB. Notice that these individual questions do not give a specific time period. You will be asking about the average use of **coffee, tea, and soda** before the NOIB pregnancy. (The investigators are not asking about hot chocolate or cocoa).

Interviewers should **not** record different brands of soda that the mother initiated drinking only **after** she became pregnant. The questions request the brands that the mother drank **before** she became pregnant.

**D19-D20** These items ask for the number of cups of caffeinated (regular) coffee and caffeinated tea the subject usually drank. Choose one category from the pull-down menu of responses. For example, 1M means 1 cup per month. (These are the same response categories as the Dietary Assessment D18 series.) If needed, you may read the responses for each item or use the list to prompt.

**D21-D25** This series asks about **sodas** and soft drinks. Select the closest category of brand name plus flavor combination on the pull-down menu. You may use the list of sodas in the CATI to probe. For each brand/ flavor, CATI then guides you to ask if it was diet (**D23**), and then to ask if it was caffeine-free (**D24**). CATI automatically provides the response for some items because the caffeine content often is linked to particular brand/ flavor and diet combinations. Choose one category from the pull-down menu of responses in **D25**. For example, 1M means 1 glass (can, bottle) per month. (These repeat the response categories from the Dietary Assessment D18 series.) Read the responses for each item or use the list to prompt.

If the subject drinks many kinds of soda, you may **probe for the five types of soda that she drank most often**: “Which five did you drink most often?”

**D26-D28** Notice the time period is during the pregnancy with NOIB. These items determine whether the subject drank more, less, same, or none of each of the types of beverages. Select the appropriate response. In some cases, the options “same” and “none” may be equivalent. You may select either option. For example, Mom may report NO to D21, that she never drank sodas. A correct response to D28 could be either “same” or “none”.

Sometimes these questions confuse mothers that are asked to choose if they drank “more, same, less, or none”, when they answered No to any of the first 3 questions (when both “same” and “none” apply). However, no change will be made in the wording or items at this time. Interviewers may explain to subjects that either the “same” or “none” response is OK in such situations.

## SECTION E: TOBACCO

### Tobacco--Mother

**E1 & E2** This question asks if Mom ever smoked cigarettes in her life, then **E2** asks for any smoking frequency, no matter how little, during the year from -3 to DOIB.

Some mothers may not understand the question “Did you ever smoke cigarettes?” to refer to lifetime smoking because most survey questions have been asking about the pregnancy time period. When asking the question, interviewers may emphasize the word “ever”; then mothers usually understand the meaning to refer to lifetime use.

**E3** This question elicits which months Mom smoked during the year (in categories from Months -3 to 7+). CATI provides “Used Every Month” and “Fill Rest with No” buttons.

**E4** This question asks for the frequency per day for each month. Select one response code for each month that was YES in **E3**. The table allows you to represent changes in frequency over the year. Probe by asking “Did you continue to smoke that many cigarettes through (last month stated)?” CATI provides a “Ditto Cigarettes/Day” button.

You may use the response menu list to prompt. Notice that the categories increase from top to bottom on the response menu. “<1,” “1,” and “2-4” refer to individual cigarettes. The next frequencies are in packs. Refer to the ranges below for numbers of cigarettes per pack.

½ Pack:	5-14 cigarettes
1 Pack:	15-24 cigarettes
1 ½ Pack:	25-34 cigarettes
2 Packs:	35-44 cigarettes

### Tobacco--Household

**E5** **E5** begins with a script for passive smoking exposure, then asks if anyone smoked at home (from -3 to DOIB). If someone smoked, but always left the house to do so, this can be recorded as a NO.

**E6** **E6** tells which months someone in the subject’s home smoked during the year (in categories from Months -3 to 7+). Use the “Yes Every Month” and “Fill Rest with No” buttons to facilitate recording the months.

**E7-E8** These two questions elicit passive smoking exposure at other places where Mom spent a good deal of time. This would also include places she did volunteer work. Refer to the instructions for **E5-E6**.



## SECTION F: ALCOHOL

**F1** The first question is written so that you define the kinds of alcoholic beverages. Be sure to finish the text before you accept an answer. In this instance or others like it, if you feel an explanation is needed, you may say, “Excuse me. I am instructed to read the entire question before accepting an answer.”

Standard serving sizes are:

**beer** = a 12 oz. bottle or can

**wine** = a 4 oz. glass

**liquor** = 1 oz. shot

**F2** Select all of the months in which Mom drank any alcoholic beverages. CATI provides buttons for “Used Every Month” and “Fill Rest with No”.

**F3-F5** CATI will guide you to repeat **F3-F5** for each month the subject drank any alcoholic beverages. After obtaining the frequency in a specific month (**F3**), then stay with each month in question and ask **F4** to determine the average number of drinks consumed on the days she had the beverages, and **F5** to determine the greatest number of drinks on one occasion in that month. If Mom says she cannot give exact numbers, tell her that her estimate is good enough. She may give an answer according to her usual habits, or she may have memories of special events.

CATI provides a “Ditto Usage Pattern” button to facilitate recording similar use patterns.

“0” is used for “less than one per day.” For example, record ½ glass of wine as “0”. A fifth of liquor = 750 ml. or 25.4 ounces. Record this as 25 ounces or drinks.

**F6** This question does not distinguish among different months, but refers to usual types of alcoholic drinks across all months. Read the entire list of alcohol types and record a response for each type. CATI provides a “Fill Rest with No” button. Specify the type of “other alcohol” if appropriate. Wine includes sherry and wine coolers.

## SECTION G: SUBSTANCE ABUSE

- This section begins with questions about NOIB’s father, then asks the same items about NOIB’s mother.

### Substance Abuse--Father

**G1** Notice this item asks about NOIB’s father and his use of **recreational or street drugs** from -3 to DOIB. If Mom had reported not knowing who the father was, this section will automatically be skipped. Read the entire list of drugs and record a response for each drug.

Be sure to read the drug list in a matter-of-fact tone to convey that these are important questions. Do not feel apologetic or embarrassed. The subjects have been told that they can refuse to answer any question. Leave this responsibility to them. If they do refuse these (or any other) questions, say “All right” or “That’s fine” and proceed with

courtesy.

FYI, we feel that if we state anything to the effect that sensitive questions are coming up, or that they may refuse to answer questions coming up, this is like raising a red flag and causes more anxiety than not saying anything at all.

**G2-G3** If YES to G2, use the alphabetical pull-down menu in **G3** to select all other drugs that NOIB's father used. Notice you must use the scroll bar to see the entire list. Probe by asking "Did he use anything else?" You may read the list as a prompt. If more than one type, record each drug separately. Do not include father's alcohol use.

If subject reports a drug type that is not on the list, specify it by typing the name in the response box.

**G4-G6** CATI will guide you to ask this series for each drug reported in G1-G3. For each drug, record all the months that Dad used it (**G4**). CATI provides buttons for "Used Every Month", "Fill Rest with No", and "Ditto Usage Pattern".

**G5** Select the appropriate mode of use from the pull-down menu (e.g., drink it, eat it, smoke it). The mode is asked only one time per drug, i.e., for the first month of use.

**G6** Record the number of times Dad used the drug, being careful to specify per day, week, or month.

CATI creates tables for different patterns of use for each month so that if the mode of use or frequency changed over the year, the detail can be shown. If Dad used a drug for more than one month or stopped and started, you may ask, "Did he change the way he used (substance) ... or the number of times per week ... from (month) to (month)?" Use the "Ditto Usage Pattern" button if the pattern is the same in every month.

## **Substance Abuse--Mother**

**G7-G12** This series asks about the subject and her use of recreational or street drugs from -3 to DOIB. Follow the instructions above for **G1-G6**.

## **SECTION H: HOME ENVIRONMENT**

**H1-H4** We are asking for residences only for the year -3 to DOIB, for more than a month. A short stay at a relative's house will be counted (if it was more than a month). Vacations will not be counted.

After recording the number of residences in **H1**, ask **H2** to determine the full address where the subject lived in Month -3. If Mom wants to know why or sounds skeptical about giving her street address (**H2**), you may say that the investigators are interested in the source of water there.

Repeat **H2-H4** for every residence. Probe by asking "What was your address after that?" Attempt to record the subsequent residences in sequential order, whenever

possible. Use the scroll bars at the bottom and far right of the tables to move among residences. CATI provides “Add Residence” and “Delete Residence” buttons. Be sure your cursor is in a blank table to add a new residence; otherwise you will erase or write over the information for another residence. To erase a residence and its record, be sure to click the gray selection bar on the left and press delete.

**H3-H4** Record the month and year Mom started living there (**H3**), even if it predates Month –3. If Mom currently lives there, then record the month and year of the interview (i.e., “today’s” date) as the stop date in **H4**.

**H5 (deleted)** Question **H5** pertaining to residential water sources was deleted from this part of the questionnaire and moved to the Water Module at the end of the interview.

### Home Environment--Hot Tub/Sauna

**H6** This question separately asks about use of a **hot tub/Jacuzzi, a very hot bath, and/or sauna** from –3 to DOIB. Record a response to each. These items appear at this point in the survey because they are related to heat (rather than to water).

“Very hot bath” refers to baths in a tub using very hot water. If a mother is not sure “how hot” a very hot bath would be, interviewers may clarify with a **probe** that “**the temperature would be uncomfortable to get into at first.**”

CATI then guides you to ask **H7-H10** for each one used.

**H7** Select all months during which the hot tub/bath/sauna was used. CATI provides “Used Every Month” and “Fill Rest with No” buttons to facilitate selecting the months.

**H8-H9** CATI guides you to ask these questions for each month the subject used hot tub/bath/sauna. In **H8**, choose from 0 to 31 to record the number of times per month. The response “Everyday” can be recorded as 30 times.

In **H9**, select one response category showing ranges of minutes. CATI provides a “Ditto Usage Pattern” button to facilitate recording similar response patterns.

**H10** This new question asks whether the hot tub/Jacuzzi or sauna was chemically disinfected. Chemical disinfection includes not only chlorination (chlorine), but also other chemicals or processes such as ozonation (ozone) and bromination (bromine). (This question is not asked for baths or saunas.)

## SECTION I: MOTHER'S OCCUPATION

### Mother's Occupation

**I1** Read the lead script carefully because it defines the types of job(s) Mom should include in her response to I1, including full and part time, paid and volunteer work. If Mom had any kind of job(s) during the year –3 to DOIB, CATI will guide you through **I3** through **I20**. If she was not employed or was employed very sparsely for the year, probe for volunteer work. Volunteer work that involved an exposure (drugs or anesthetic gases in health care settings, hazardous chemicals, solvents, computer terminal work) should be recorded in the job table also.

It is not necessary to probe to determine whether the mother took time off for pregnancy leave, e.g., when she had the same job throughout the period. However, if the mother offers the information, then interviewers should make a note of it and record the work as separate time periods.

If the mother works for one temporary agency but for multiple places, then interviewers should record each separate job if the jobs are different types of work. However, if the jobs are the same type of work, then it is not necessary to collect information on each separate job. Details should always be recorded about the main activities, duties, and exposures.

Sometimes subjects think it is silly to be asked what the company made or did, because it seems self-evident. Interviewers may let subjects know that you must to ask the question, even though it seems obvious. For example, interviewers may state "I know it seems obvious, but I have to ask you..." Some interviewers change their tone of voice.

**I2** For Moms who did not have any jobs, read the entire list of options to determine if she was a homemaker/parent, disabled, a student, or unemployed from –3 to DOIB. CATI then guides you to questions about Mom's military service.

**I3** Record the name of the company for each job (from –3 to DOIB). Include self-employed. Probe by asking "What other company (or organization) did you work for?" If Mom wants to know why we are asking for her work address, you may say that the investigators may want to study occupational exposures at certain kinds of companies in the future, but that her name would not be used, as promised.

**I4** Record each job title for each organization. If Mom has more than one job title in the same organization, then repeat the organization name and record each job title in separate rows.

We will use the U.S. Census Bureau Industry and Occupation codes for kinds of companies and for job titles. If the company is a conglomerate, like Northern Telecom or IBM, ask what the division she works in does or makes. That information will be used in coding to define the industry she worked (works) in.

Do not include organizations/jobs that exclusively occurred after the DOIB. However, you may include jobs that ended in or after DOIB month.

- I4-I7** We will use **I4-I7** responses to produce U.S. Census Bureau occupation and industry codes. If Mom's job title is not very descriptive, we will be looking at her duties for clues. Three professions require certain detail to code. For **teachers**, we need to know whether elementary, junior high, high school, or college instructor. For **farmers**, we need to know whether they work with crops or animals, or both. For **engineers**, we need to know what kind, as in electrical, mechanical, aeronautic, etc.
- I8-I9** Record month and year that each job started and ended. For **I9**, if Mom still had a job technically, but left for early pregnancy leave or took a leave of absence for any reason, we want to know when she actually stopped working. Show the end of job date as the date she left the workplace.
- I10-I11** Record the usual number of days worked per week (**I10**). Record the usual number of hours worked per day (**I11**). If Mom worked some kind of irregular shifts or hours per week that do not seem to fit in the boxes, write a Comment.
- I12** **I12** refers to all jobs between -3 and DOIB. Read each exposure category and select a response for each. Be sure to read the entire category (e.g., "ionizing radiation such as x-rays") before accepting a response. (It is not necessary to link particular jobs to particular exposures.)
- CATI then guides you through **I13-I15** for each YES.
- I13** CATI creates a table for each type of exposure from I12. Record the names of the products in **I13**. Try for a chemical name(s). If Mom cannot be specific, write a descriptive note. (CATI provides space to record the name of one product for each exposure type.)
- NOTE:** CDC may modify the CATI format so that different use patterns can be recorded for multiple products under each exposure types. Currently, CATI only allows one product per type of exposure. Use the Comment button to describe additional exposure types.
- I14-I15** CATI displays the exposure type in the upper right side of the screen for **I14-I15**. Specify the months used. Then, select the number and specify hours or minutes of the monthly exposure. If there are no hours or minutes, select between the categories "< one/week" or "one time exposure only".
- CATI provides buttons for "Used Every Month", "Fill Rest with No", and "Ditto Usage Pattern".

### **Mother's Occupation--Military**

- I16** This gateway question determines if Mom was on active duty in the United State **armed forces** since January 1, 1990.
- I17** Select the country from the alphabetical pull-down menu. Select as many countries as apply. (CATI sets up separate tables and menus for each country and/or tour of service.)
- I18-I20** CATI guides you through the **I18-I20** series for each country. Record the month and year for the start and end dates of service in that country.

Record the chemical or biologic name(s) in **I20**. If Mom cannot be specific, write a descriptive note. Select “None” if appropriate.

## **SECTION J: FATHER’S OCCUPATION QUESTIONS**

### **Father’s Occupation**

**J1-J11** This series obtains information about NOIB’s father’s job(s) during the period –3 through DOIB. Follow the instructions above for **I1-I15**.

If the respondent did not know the father, CATI will automatically skip to J17.

### **Father’s Occupation--Military**

**J12-J16** This series obtains information about NOIB’s father’s active military service since January 1, 1990. The same specifications apply as for **I16** through **I20** above.

### **Occupation--Pesticides**

**J17** This gateway question determines if any household member applied **pesticides** as an occupation or as part of their work, from –3 to DOIB.

**J18** Record the number of times that Mom personally washed clothing that someone wore to apply pesticides (or, select the “never” category). Specify if the number of times was per day, week, month, or year, or specify “other”.

## **SECTION K: FAMILY DEMOGRAPHICS**

- The lead-in to this section mentions the subject’s ethnic background and education.

### **Family Demographics--Mother**

**K1-K2** **K1** gateway question establishes if Mom was born in the United States. If YES, skip to K3.

**K2** If not, ask **K2** (“Where were you born?”) and select the country of her birth from the alphabetical pull-down list.

**K2A** If NO to K1 (i.e., she was not born in the U.S.), **K2A** asks the number of years the subject has lived in the United States. Record the number.

**K3** Select the language the subject usually speaks at home from the pull-down menu. Specify if Other.

**K4** Read the list of **rac~~es~~/ethnic groups** to the respondent. Again, the rule concerning reading lists is that you make sure the mom heard the entire list before accepting an answer. Specify if Subject gives an “Other” response or gives multiple groups and does not want to choose just one category. Note that the pre-coded category “Hispanic” is reported separately from Black, White, and other groups. However, for example, Hispanic could be reported under the “Other Specify” category in combination with White, Black, or another group.

If Mom is an Asian or Pacific Islander, ask from which country she came, and select her response from the pull-down menu. Specify if “other”. If she is an American Indian or Alaskan native, specify to which tribe she belongs. For people who report a particular ethnic group or mixed race, write verbatim in the “other/specify” space.

When subjects report they are Indian, the interviews should ask, “is that Native American or from India?” If from India, the Asian/Pacific Islander choice should be selected and the country filled in as India.

**K4-K5** If Mom responded that she is Hispanic, then CATI asks **K5**. Select her response from the Spanish/Hispanic groups in the pull-down menu, or specify in “Other”. (If Mom responded Hispanic and another group in the K4 “Other Specify”, the CATI will not automatically go to K5 so you may probe by asking, “Which Hispanic group do you consider yourself a member of?”, and record her response in a comment.)

**K6** It is not necessary to read the education categories if a response is volunteered. It is your responsibility to select the appropriate category. If Mom hesitates, read the list to prompt a response.

**K7** **K7** is phrased to cast a broad net for birth defects. Whatever Mom considers a problem at birth or a defect diagnosed in childhood is acceptable. CDC birth defect codes will be applied later. Record as specific or as complete a description as is practical. If there is not enough space in the response box, use the comments button to record additional details about the defect.

If a respondent indicates “No” to a birth defects question, and then states “but (person) had (health problem),” key in her response (No) and then document the health problem under Comments.

## **Family Demographics--Father**

**K8** Notice that the lead script indicates questions **K9-K22** are about NOIB’s biological or natural father. Remember that Mom may never have been or may no longer be married to the father, so never refer to him as her husband unless she does so first. If you sense that she is more comfortable with “husband”, then it’s all right for you to call him that.

If the mom said she did not know the father at all, CATI will skip over of all questions about the father and his family.

**K8-K13** These questions follow the same specifications as **K1-K7** for the mom.

**K14-K15** If Mom was **related to NOIB's Father by a blood relative**, select the relationship from the pull-down menu. Specify any "Other" relationship. Be especially careful to ask this question in a neutral and non-judgmental manner. Some subjects may laugh, or may be offended by the question; just tell them you must ask everyone the same questions. If Mom wants to know why we ask the question, you may say that the investigators are looking for inherited relationships.

### **Family Demographics--Relatives**

**K16** This gateway question asks whether any of NOIB's relatives had a health problem at birth or birth defect. It includes relatives in the mother's and father's families. It includes full and half siblings, grandparents, aunts and uncles, and cousins. If you select "cousin", CATI will ask the sex of the cousin. All other relationships are sex-specific.

If Mom wants to know why we only want to know about blood relatives, you may say that the investigators are looking for inherited relationships. If the person was adopted, record full and half brothers and sisters, if known. If unknown because of being adopted, then write a note "don't know because adopted".

If NO or DK, skip to K20 (income).

**K17-K19** CATI will guide you to repeat K17-K19 for each relative with a birth defect. Record the relationship of each relative that had a birth defect (select from the pull-down menus). If the relationship is "Other," you do not need to specify the type in the text box or as a Comment.

Again, record whatever the mom considers a birth defect to be. If there is not enough space in the response box, use the comments button to record additional details about the abnormality.

### **Family Demographics—Household Income**

**K20-K21** These questions were added to capture **household income** and the number of people supported by that income. The first question captures those with incomes under 10 thousand and those over 50 thousand. Those answering "in between" will be asked the next question to determine what 10 thousand dollar range they're in.

**K21** This question includes all adults and children supported by that income in the year **before** she became pregnant with the index baby.



## SECTIONS L – P: WATER MODULE

### General Instructions

- **Sections L through P** consist of the Water Module. Most of the Water Module questions in these sections cover the time period (-3) through (DOIB), although some water questions are limited to a shorter period or only one residence.

### Background and Rationale of Water Module

- The following summary by Dr. Michele Lynberg describes the rationale for the Water Module. It is for information purposes only.
- Chlorination of drinking water has benefited public health enormously by lowering the rates of infectious diseases spread through untreated water. On the other hand, recent epidemiologic studies of disinfection byproducts (DBP) and adverse reproductive outcome in California, Iowa, New Jersey, Massachusetts, and North Carolina have suggested an association between DBP in tap water and a number of outcomes (including spontaneous abortion, birth defects, intrauterine growth retardation and others). In general, the reported risks in these studies have been relatively consistent, but modest in magnitude. The studies are generally based on small numbers of cases, making interpretation difficult. It is important to consider, however, the reported studies were done in areas with unextraordinary DBP levels. Because of the ubiquitous nature of such exposure, even relatively weak risks (if confirmed) are of potentially great public health importance. More research on the potential relationship between DBP and birth defects may provide important information to protect human health from potentially harmful effects of contaminants in drinking water.
- The NBDPS drinking water module compares a number of classification methods for characterizing exposure to DBP in drinking water. By identifying differences in these methods, the study will expand the currently limited knowledge about water use and consumption habits that influence an individual's exposure to DBP. A number of approaches to exposure classification are being used, including reported consumption and reported use (other than drinking) and information gathered from the utilities. It is important to note that in the past, drinking water has been the primary focus. However, recent studies have shown that other routes of exposure (inhaling and absorbing through the skin) are at least as important and maybe more so. The relative importance of drinking, showering, bathing, and other household activities is currently unclear.
- Prior to the NBDPS, no birth defect studies have been done which considered all routes of exposure. This study is intended to address these issues, in as short a time frame as possible. We accomplish this by obtaining reported exposures and by gathering data from water utilities information. Reported water consumption/use and utility data can be used to define exposure separately and in combination. (In other words, reported exposures are useful in and of themselves).
- Because of time limitations, we had to make some compromises. For example, we only ask detailed questions about the water source at one residence (the earliest residence of the pregnancy). Optimally, we would collect this information at all residences. But the data collected are none-the-less useful, especially in terms of routes of exposure other than drinking. In addition to the residence we ask about in the water module, we will be able to link utility data for other addresses the mom lived at during her pregnancy. These can be linked with all routes of exposure.

## SECTION L: HOME WATER ENVIRONMENT

- Read the introductory Opening Statement that mentions the (-3) to (DOIB) time period for these items about water use at home and away from home.

**L1-L11, M1-M4** The first series of questions (questions **L1-L11 and M1-M4**) will be asked for one residence only. The CATI will insert the address for the residence where the mom lived during the first month before pregnancy (i.e., B1, to capture the first trimester of pregnancy). The CATI selects the residence where the mother was living in month B1 (-1), i.e., one month before pregnancy. If more than one month straddles this category, then CATI selects just one of them.

The CATI program is date-sensitive, and will not pick up a residence with “don’t know” or “refused” in the starting month and year. If the starting month is “DK”, then CATI will treat it as “January” of that year. Therefore it is very important for interviewers to probe for these dates to obtain both specific starting month and starting year, whenever possible.

If the mother did not provide a residence for that time period (e.g., did not know or refused), then the CATI will skip this set of water items pertaining to a residence.

The single residence and limited time frame are used in these items to limit the length of the water module.

**L1** Private well/tap water: Record Yes or No to this gateway item asking if the source of tap water is from a private well. The CATI inserts the address of mother’s residence into the stem of the question. CATI asks about only one residence (i.e., month B1, one month before pregnancy).

Some residences will not have tap water. Select “NA” for Not Applicable if the subject did not have tap water in her house. CATI will skip any related items.

Many subjects get confused about private well water, especially when they don’t have a private well, but even when they live in rural areas where private wells might be common. When subjects are confused, interviewers may probe by asking something like “**Was the source of water at (residence) from a city water source or a private well?**” If the person “doesn’t know”, interviewers may also ask, “**What was the source of your water?**”, or does their water come from a water treatment plant, or does the community they live in have a water treatment plant.

**L2** Private well disinfection (if Yes to L1): “Chemically disinfected” includes not only chlorination (chlorine), but also other chemicals or processes such as ozonation (ozone) and bromination (bromine).

**L3** This gateway question determines whether the tap water used for drinking or cooking was filtered. Response options are Yes, Sometimes, and No -- you may read those options if needed. Select “NA” for Not Applicable if the subject did not have tap water in her house.

Sometimes subjects may not hear the entire gateway question about the source of a filter on tap water, and may think they’re just being asked about using filtered water.

In such situations, interviewers should first repeat the question with emphasis on the key terms, but then may also **probe** further to clarify the meaning of the question by asking **“Do you filter your tap water?”**

Use the below definition of **filtered water**. Include portable filters, filter pitchers, etc. and filtered bottled water.

**Definition of Filtered Water:**

- **Filtered water** refers to water that came from the sink (or tap) but ran through a special device to remove impurities. Filtered water can include water that is filtered by filtration system for the entire house or for a particular location in the house, or by a portable filter including pitcher with filter insert. It also can include filtered bottled water. (Britta is a common brand of portable filter pitchers to be included as filtered water.)
- Water softeners should be excluded; they are not counted as filters (e.g., water softeners add a form of salt to the water).

**L4** (If Yes or Sometimes to L3): Record whether the filter system is for the entire house or for specific locations within the house. If certain locations, then list all of the locations specifically such as kitchen sink faucet, master bathroom sink faucet, guest bathroom sink faucet, etc. Also include portable water filters, filtered bottled water, and filter pitchers under the “Specific locations” category. (Britta portable filter pitchers would be specified here.)

**L5-L8** Questions **L5 and L6** will be asked for the entire house. The same questions **L7 and L8** will be asked for each specific location within the house.

**L5** Type of water treatment/filtration system in entire house: Read both response options Membrane Filter or Charcoal Filter to the mom. If a mom answers something other than the listed responses, please record her answer in the box next to “Other.” If mom says “don’t know”, **probe** by asking **“Do you know the brand name of the water treatment/filtration system?”** Brand names include Britta, Amway, Pure, and Puriclean. Record her response on the line after the question.

**L6** For entire house: How often did you change the filter? Record the number of times. Response options include less than once per year (“<1 per year”) and “self-cleaning”.

**L7-L8** Filtration system in specific location. These questions are asked for each specific location. Refer to the instructions for L5 and L6.

**L9** This gateway question asks if there was a **filter on the showerhead**. Record Yes or No.  
This item confuses many subjects, for example, who may think we are asking about showerheads in general or shower massage units. Interviewers may **probe** by providing a clarifying statement such as **“a filter on your showerhead that takes out chemicals”**. (In the future, the position of this item in the questionnaire may be moved to a later section after we ask all other questions about shower usage.)

**L10-L11** If Yes to L9, record the type of filter for the showerhead (**L10**), and how often that filter was changed (**L11**). Refer to the instructions for L5 and L6.

## SECTION M: DRINKING WATER AT HOME

- Section M begins with a general script that leads into questions about the subject's home water use from (-3) to (DOIB).
- Read the introductory sentences that tell the mom that these questions only include water she drank or used at this home address. (Water use at work or school is asked separately in Section N.)

**M1-M4** Questions **M1-M4** are asked only for one residence where the mom lived during Month B1, one month before pregnancy (or in the first trimester of pregnancy).

The format of the CATI screen with these items does not clearly show in what order to ask these questions M1 through M4 (i.e., the screen format does not show obvious skip patterns). On this screen, interviewers should first read the top questions from left to right across the screen (M1 on source/types of drinking water and then M2 on amount for each type). Then read the bottom questions across from left to right (M3 on hot drinks and then M4 on cooking water). Of course, interviewers can follow the "cursor" when tabbing through the items to determine the appropriate order.

**M1** Read the **source types of drinking water** at the specified residence to the mom – Unfiltered tap, Filtered tap, Bottled, or Other. Check all that apply. If a mom answers something other than the listed responses, record her answer in the box next to "Other."

**M2** Ask **amount for each type** of water that the mom said she drank in M1. (CATI will display only the sources that were checked in M1.) For each type, record the number of glasses (8 ounces), and whether the period was per day, week, or month. (Although the question asks for the number per day, the mom may respond in weeks or months instead.) Do not record water used in coffee or other hot drinks; only include both plain water and water used to make cold drinks such as frozen juice, lemonade, powdered ice tea, powdered drinks, etc.

When you ask a mom how many glasses of a particular type of water she drank and she gives you a range, like 4 or 5 glasses, ask, "Which would you say...". If mom still cannot decide, ask for her "best guess."

**M3** **Hot drinks from water (at home):** Read response options -- Unfiltered tap, Filtered tap, and Bottled -- to the mom, but do not read the choice for "Other". If mom says she never drank any hot drinks, then check "NA" for not applicable.

**M4** **Water in Cooking/Food Preparation (at home):** Read response options -- Unfiltered tap, Filtered tap, and Bottled -- to the mom, but do not read the choice for "Other".

**M5-M8A** **Changes in Drinking Water Habits:** Questions **M5 - M8A** refer to the entire time period (-3) to (DOIB), and can refer to any residence or location. They are not linked to a particular residence or trimester. Instead, the focus shifts to the time period (-3) to (DOIB) (which may or may not correspond to a particular residence). These items are not limited to residences but also include water drunk at school

and/or at work. Read the introductory sentence that alerts the subjects that these questions will ask about the entire time period from (-3) to (DOIB), and not just one residence or location.

**M5** This gateway question was revised to ask whether the mom changed the amount of water she drank at any time during her pregnancy. The time period is for the index pregnancy, when Subject was pregnant with NOIB.

**M6** CATI automatically embeds the month/year that the pregnancy began into this question. If there was a change, record the month and year the change occurred. If the subject does not remember the month and year, then she may remember the number of weeks she was pregnant. Either will do. Only if the subject cannot recall either the month and year or number of weeks pregnant, is it acceptable to **probe** with **“During what trimester did the change occur?”**

**NOTE:** Interviewers must record the number of weeks pregnant in a Comment, because the current CATI does NOT provide coding place for Trimester/Month of pregnancy for this item.)

Many subjects feel confused about these questions. If there is confusion about the dates when a change occurred, interviewers and subjects should focus on the identifying the “month and year” the drinking habits changed, and use that date as the referent for the subsequent items M7 and M8.

**M7** Record that she either drank “more” or “less” water (since the date in M6).

**M7A** Record the number of glasses (8 ounces), including water used to make powdered or concentrated drinks. Just record the number additional or fewer glasses that were drunk, not the overall total.

**M8-M8A** The gateway **M8** determines whether or not the subject switched the source of drinking water during (-3) to (DOIB). If Yes, record the source/type of water she switched to in **M8A**. You may read the response options.

## **SECTION N: DRINKING WATER AT WORK OR SCHOOL**

- **Section N** questions are only asked for those moms who said during the interview that they were employed or attended school between (-3) and (DOIB). Read the introductory sentence. Record responses for each job the mom held or school she attended from (-3) to (DOIB).

**N1** **Deleted item.**

**N2** The CATI will insert the name of the job/workplace or school in the stem of the question. Read response options to the mom for water sources at the workplace/school. Check all that apply. Include hot and cold drinks.

Check the box for “Not outside the home” if the subject did not attend school or work outside of her home.

Select “NA” for Not Applicable or None if the subject did not drink any water at the

workplace/school. CATI will skip any related items.

**N3** Ask amount for all types of water that the mom said she drank in N2. (CATI will display only the types that the mom used in N2.) Do not record water used in coffee or other hot drinks. Only include both plain water and water used to make cold drinks such as frozen juice, lemonade, powdered ice tea, powdered drinks, etc. (Refer to instructions in M2.)

This item excludes hot drinks, although N2 included hot drinks. CATI should include a “0” as a response option if the mother says she drank only hot drinks at work/school. (**NOTE:** If “0” is not an option, select “<1” and record a Comment.)

When you ask Mom how many glasses of a particular type of water she drank and she gives you a range, like 4 or 5 glasses, ask, “Which would you say...”. If Mom still cannot decide, ask for her “best guess.”

## **SECTION O: HOME WATER USE ACTIVITIES**

- Read the introductory sentence about other uses of water at home from (-3) to (DOIB).

**O1A-O1E** Each activity **O1A through O1E** must have a response. Even if mom answers “none”, record a “Never” in the box next to the activity. The basic stem of the question has been revised to ask how often the mother performed each activity, and the mom’s responses may be recorded as the number of times per month, week, or day. (The response options are the same as the Food Frequency choices.) Previously, the items asked how many times per week the mother did each activity.

When you ask Mom how times she washed dishes, clothes, or children and she gives you a range, like 4 or 5 times or minutes, ask “Which would you say...”. If Mom still cannot decide, ask for her “best guess.” Interviewers may use the response options to probe and help the mother specify her answer.

**O1D** Bathing children refers to tub baths. If a mom says that she showers any children, say: “Please only include time when you were in the bathroom with the child, time that does not include when you were showering yourself.” If a mom says she showers with a child, tell her to include cases when she showers herself and a child at the same time in the next section when you will ask about her own showering practices.

**O2** This revised gateway item asks how often the subject used the washing machine at home. The time period is (-3) to (DOIB) (see instruction to O1.). (Previously, O2 and O2A were a single item. The “old” data for the previous wording of this item will be in the background in the data tables, but interviewers and supervisors/data editors will not be able to see that those questions were answered previously.)

Subjects should only report laundry washed in her washing machine at home. Do not count laundry done at a commercial Laundromat or in the laundry facilities of the subject’s apartment complex. It is not necessary to write a comment when the subject washes laundry at facilities other than in her home.

- O2A** Average number of loads of laundry each time: Even if mom answers “none”, please record a “Never” in the box next to activity. (See instructions for O1.) If clarification is necessary, interviewers may emphasize that the question asks for an “average” number of loads. (Notice in the revised items that the time frame will vary depending on the response in O2, and does not specify “per week”.)
- O3** Mom’s showers do not include tub baths. Include any showers that a mother takes herself while also showering a child. Only include showers taken at home, not at other places. If mom answers “none”, record a “Never” in the box.
- Record mom’s showers in series O3-O6 and baths in series O7-O10.
- When you ask Mom how many showers she took or for how many minutes she showered and she gives a range such as 4 or 5, ask “Which would you say...”. If Mom still cannot decide, ask for her “best guess.”
- O4** Record the number of minutes the mom spent in the shower each time.
- O5** Window open when showering? Read the options Usually, Sometimes, or Never. If mom responds that there is no window in her bathroom, check NA for “Not Applicable”.
- Subjects may laugh or get confused when asked about having the window open when showering and bathing. Although the question is not clear about whether the window is in the room with the shower or tub, the item is asking about ventilation in that room. (In the future, the items about open windows may be placed after questions about exhaust fans to clarify their meaning.)
- O6** Exhaust fan on when showering? Read the options Usually, Sometimes, or Never. If mom responds that there is no exhaust fan in her bathroom, check NA for “Not Applicable”.
- O7-O10** Mom’s Tub Baths: Repeat the O3 through O6 series for baths (in a tub) at home, following the instructions above for O3-O6. Only include baths taken at home, not at other places.
- Some subjects may become irritated about being asked about baths in the water module when they’ve already been asked about very hot baths in an earlier section. Interviewers may explain that the purpose of the earlier section on hot baths focuses on heat and temperature, while these questions about baths ask about other types of water exposures not related to heat.

## **SECTION P: SWIMMING POOL USE**

- Read the introductory sentence about **swimming pool use** from (-3) to (DOIB).

- P2** If a mom says that she doesn’t swim, repeat the part of the question that tells her that you are also interested in the time she spent exercising in a pool, standing in a pool, and time spent around a pool. Record the names and/or locations of all swimming

pools the mother used between (-3) and (DOIB). The CATI will insert these pool names into subsequent questions.

**P3** If the mother does not use the word “pool” in her response to P2, be sure to use the word “pool” in questions P3 and P4. For example, if the mother replies “YMCA” in response to P2, then introduce P3 by saying “During which months did you use the YMCA pool?” Do not say “During which months did you use the YMCA?” Record each month the mom used that particular pool.

You may use the “Used Every Month”, “Fill Rest with No”, and “Ditto Usage Pattern” buttons as appropriate.

**P4** Number of times per month mom used each particular pool: If Mom gives you a range, like 3 or 4 times, ask “Which would you say...”. If Mom still cannot decide, ask for her “best guess.” Even if Mom answers “none”, record a “0” in the box. Include pools where Mom spent time swimming or exercising in a pool, standing in a pool, and around a pool.

**P5** Record the number of minutes each time that the mom used the pool, including time in and around or near the pool. Response options are given as ranges (similar to Jacuzzi/hot tub use).

**P6** Record whether the pool was an indoor or outdoor pool, or both. “Both” is an acceptable response.

**P7** Record whether or not (Yes or No) the pool was chlorinated.

Use the Comment button to describe any other chemicals or processes that the mother may mention, such as ozonation (ozone) and bromination (bromine).



## SECTION Q: CLOSING SECTION

### Q1-Q2

**Q1** is the gateway question. **Q2** is an open-ended question that asks Mom to give causes of birth defects. If Mom seems perplexed, you may say that “The investigators are interested in what she may have heard or read.” Mom should be allowed to express her thoughts, opinions, and feelings if she prefers for a reasonable length of time. Jot down sentence fragments, giving key words (for example, people often mention smoking and alcohol) to express the essence of what she tells you.

### Q2

**Closing Statements:** In answering the closing question about causes of birth defects at the end of the survey, many mothers only want to talk about their own child’s birth defects. This is fine, it is not necessary for the mothers to respond about general causes of birth defects. The investigators are interested both in general information and perceptions and in information pertaining to specific children. Interviewers may emphasize certain words in the question to make it sound like we’re talking about birth defects in general. However, no matter how the question is asked, the mother may focus on birth defects of her own child because her experience is with her own children.

At this point in the questionnaire, some mothers become defensive and seem to feel guilty about their own behavior, and may be trying to shift blame. Some may report “Well, the only thing I did wrong was...”. If the mother questions the mother about causes or blame, or if the interviewer feels the mother may feel guilty, the interviewer may state: **“We really don’t know what causes most birth defects, and that’s why this study is so important.”** Some subjects ask why the survey did not ask more about the fathers’ behaviors and exposures, e.g., the medicines the father took, the father’s medical problems such as epilepsy. Interviewers may explain that **“This particular study only asks about mothers. ... Other studies will be necessary to learn more about the fathers’ experiences.”** Also, **researchers prefer to ask mothers and fathers to provide information about their own behaviors and experiences, rather than asking them to answer questions for each other.**

If you sense that the mother feels anxious or guilty, it is always appropriate for the interviewer to reassure the mother and remind her that we do not know the causes of most birth defects. For example, the previous birth defects study told mothers: **“We do not know if there is a link between birth defects and some of the health behaviors and things we have asked you about. Until more is learned, it may not be possible to say that any particular factors are responsible for specific birth defects. Your answers to these questions will help us greatly in our efforts to better understand the causes of birth defects.”**

### Q3-Q4

#### Debriefing Statement

- The first part of the Closing Script (**Q3**) reminds Mom that all information is confidential. If Mom is willing to give a future contact, complete the Future Contact information (**Q4**). Confirm the participant’s address. Try to obtain contact information for one person that does not live with the subject but who is likely to have a stable address and always know where the subject is. Try to obtain a work telephone number.

- Then read the second part of the Closing or Debriefing Statement. The purpose of the introductory and closing scripts is to let Mom know that she should not conclude that any of the factors we asked about could have caused her baby's defect. For Control Subjects, the scripts give perspective on others with these problems and put a value on their contribution.
- **Newsletter and Study Results:** Some mothers ask about results of the study at this point. You may tell subjects that the study investigators are producing a newsletter that will be sent to participants on a periodic basis. The newsletter is being sent to all subjects. It will not identify the subject as having participated in the study.
- Give a warm and sincere thank you. Click the box indicating that you read the closing statement.

## Q5

### **Buccal Collection Script (Closing)**

- Scripts that introduce the buccal collection are embedded after the core interview. The script informs the mother that the buccal kit will be mailed. Wording of the scripts varies automatically depending on whether the baby and/or father are living or available. All Centers use the same core script with "custom" scripts having only minor wording variations depending on each Center's protocol. Variations to the core script include (1) not mentioning the buccal collection in the advance letter (California) and (2) not receiving the \$20 incentive for the buccal (New York). The script is general concerning whether the kit contains a soft brush versus foam swab.
- CDC may build in an address correction table after the buccal collection script (for local use only).

**SECTION R: STATUS OF INTERVIEW**

- R1** The interviewer ID should be recorded here.
- R2** Specify whether this interview was done on the phone or in person.
- R3** Select the appropriate category for status of the interview you just conducted, e.g., Interview Completed, To be Continued, or Refusal/Permanent Break-off.
- R4** Enter the date interview was completed or ended.

**SECTION S: INTERVIEWER REMARKS**

- S1** After you hang up, immediately rate the quality of the interview. Select the category.

**Multiple Interview Evaluations:** In situations when more than one interviewer conducted the interview with the subject, how should the interviewer code and remarks be recorded? The protocol for handling a second interviewer will be to use the code of the interviewer that spent the most time interviewing; that interviewer should record the interviewer evaluation remarks. Also, make a note in the Comments that there were multiple interviewers as well as any remarks if different evaluations pertain.

- S2** Record whether the father contributed to Mom's answers.
- S3** Record whether another person contributed to Mom's answers by selecting from the drop down list or Other.
- S4** If the interview was questionable or unsatisfactory, select a category for the reason, or record the reason in the OTHER, SPECIFY space if none fits.
- S5** Record whether another person translated the interview, and specify their relationship and language spoken from the drop down lists.
- S6** Use the last comment space to tell about anything unusual that may have affected the validity of the interview. You may feel that the subject was honest and candid for all except one section of the questionnaire, or you may have sensed that in general she was reserved and did not like to give out personal information. Your comments can cover any issue. They are welcome and they are confidential.
- Click box if you made a comment.

## V. AFTER THE INTERVIEW

- **Editing:** As soon as you can, and before you call another subject, edit your questionnaire notes from beginning to end. Make your handwritten notes legible. Check for discrepancies and blanks.
- **Recalling Subjects:** When you cannot resolve a discrepancy or fill a blank using the information you have, you must call Mom back and get the information from her. Of course, we like to keep call-backs to a minimum. We want the interviewer who administered the questionnaire to call the subject back, so that she does not have the impression that many people are looking at her data.

**THANK YOU  
FOR YOUR TIME, ATTENTION TO DETAIL, AND PATIENCE.**

May you interview lots of nice people!

*[c: bdce training/revised bdce qxq052301.doc (5/23/2001; aw)]*

## ATTACHMENT A

### National Birth Defects Prevention Study

#### CATI KEY COMMANDS

<b>Alt + D</b>	When in medications modules screens, toggles to the Medications Details screen (from Medications Taken screen).
<b>Alt + T</b>	When in medications modules screens, toggles to the Medications Taken screen (from the Medications Details screen).
<b>Alt N</b>	Next button
<b>Alt B</b>	Back button
<b>Alt + S + Enter</b>	Starts the interview
<b>F4</b>	Shows pull-down menus.
<b>TAB</b>	Enters data and moves cursor from field to field. Proceed to next item or screen or page.
<b>Esc (Escape)</b>	Undo changes, or restore previous values. Press once to restore values in current textbox. Press twice to restore values on a page. Must be used before proceeding to the next item, screen, or page.
<b>Exit Door</b>	Icon button in top right corner of certain screens; click to close pop-up screens.

## ATTACHMENT B

### National Birth Defects Prevention Study

Centers for Disease Control and Prevention  
Centers for Birth Defect Research and Prevention

***This Infertility Primer from CDC is for interviewers for background information only. Do not provide this fertility procedure information to the mothers. It is too complicated to try to explain all of the different fertility information to the mothers. If a mother used any of these to get pregnant, she will most likely know what they are. If she is confused about the terminology, ask her to answer the questions as best she can and record her response in a comment field. If the subject asks the interviewer to explain the procedures, tell her you do not have information available to you to explain these procedures, but that you will record any information she is able to give you about the procedures she used.***

### INFERTILITY PRIMER

What causes infertility? Sperm problems are the most common and will be the major cause in 35 to 50 percent of all cases. Egg or ovulation problems comprise 15 percent and tubal problems 15 to 20 percent of cases. Another 15 percent of couples have "unexplained infertility," and about 25 percent of infertility cases have more than one factor--so these numbers don't have to add up to exactly 100 percent. Age also has a strong impact on a couple's infertility, regardless of the etiology. Conventional treatments such as fertility drugs (often used in conjunction with IUI—intrauterine or "artificial" insemination) and surgery can help many couples, but not all.

**Male infertility** is easier to detect but more difficult to correct than female infertility. Normal sperm counts range from 20 million to 60 million cells per milliliter (one-fifth of a teaspoon) of semen. Anything below that means a low sperm count, the most common cause of male infertility. About half the cases of low sperm count are caused by varicoceles (varicose veins in the testicle), or blocked sperm ducts, often due to scarring from sexually transmitted diseases (STDs). **Microsurgery** can be effective for both, and **fertility drugs** may help the next most common cause: hormonal deficiency. All-out testicular failure can be caused by a range of traumas—including mumps, STDs, and injuries--and is more difficult to treat. Another 10 percent of infertile men have antibodies that destroy their sperm as soon as it's produced. Whatever the cause, IUI and ART (assisted reproductive technology) are often employed to boost the chances of sperm reaching the egg.

In **female infertility**, ovulatory or endocrine problems account for about half of all cases. Common causes include failure of the hypothalamus to induce ovulation, polycystic ovarian disease, and premature ovarian failure. In luteal phase dysfunction, there is not enough progesterone after ovulation (the "luteal phase") to support the implantation of a fertilized egg. Oral contraceptives may also render a woman anovulatory after she has stopped taking the Pill. Many of these problems are treated with **ovulation-inducing drugs** plus IUI.

Obstructions within the reproductive system account for another 40 percent of women's infertility; the leading cause is pelvic inflammatory disease (PID). Twenty years ago, blocked fallopian tubes, pelvic adhesions, and scarring--which can all prevent the egg and sperm from connecting--caused only 25

percent of female infertility. But as men and women have become sexually active earlier and with more partners, the number of pelvic infections caused by sexually transmitted bacteria has multiplied. Barrier contraception protects a woman's reproductive system, but the IUD renders her up to 10 times more likely to contract PID. The second most common cause of obstructions is endometriosis: the blood-rich lining of the uterus escapes and grows on the ovaries or tubes, creating adhesions. Although **microsurgery and laser surgery** often restore blocked tubes, they do not always restore fertility, at which point couples turn to IVF.

Looming over all these factors is the factor of age. Aging decreases fertility in both sexes, but more dramatically in women. A woman under 30 has a 20 percent chance of becoming pregnant in any given month, but once over 40, her chances plummet to 5 percent. She begins her reproductive life with 300,000 eggs, but only a few thousand remain when she is in her forties. Older eggs do not fertilize as easily, do not respond as well to reproductive hormones, and have a higher number of chromosomal problems. Therefore, the risks of miscarriage, or of bearing a child with genetic disorders such as Down syndrome, increase steadily with age.

Infertility is diagnosed after a woman or a couple has tried to achieve pregnancy for a full year and failed, since it takes, on average, six months to conceive. According to some estimates in the popular press, there are 9 or 10 million infertile couples of childbearing age in the United States--or 1 in 6 couples--and infertility is reaching "epidemic" proportions. But the National Center for Health Statistics contests this view, reporting that about 4.9 million women between the ages of 15 and 44 were infertile in 1988 (or about 1 in 12). These women represented only 8.4 percent of their age group; in 1965, the percentage of infertile women in the same age group was 11 percent.

The public perception that infertility rates are rising is due, in part, to extensive media coverage of new reproductive technologies and to the proliferation of fertility clinics (from 30 to 300) in the last decade. The huge cohort of baby boomers has also produced "a big bubble of childless women," as one reporter called it. The common practice of delaying child-bearing until couples are in their thirties (20 percent of U.S. women begin their families after age 35) increases the time it takes to conceive naturally, as well as the pressure to conceive quickly. And several international studies have reported dramatic declines in sperm counts, possibly due to environmental causes.

### **The Science of Assisted Reproduction**

In 1978, Louise Brown, the first "test tube baby," was born in England. For the first time, a woman with blocked fallopian tubes who could not be helped by conventional surgery could hope to conceive and bear her own child through in vitro fertilization. In IVF (in vitro fertilization), a woman's ovaries are drug-stimulated to produce 10 to 20 eggs, rather than the normal one or two. When mature, these ova are surgically "harvested," or retrieved. Each egg is then combined with 75,000 to 100,000 sperm in a glass petri dish--hence in vitro ("in glass") as opposed to in vivo ("in body"). The next day, two nuclei mean that fertilization has occurred. Forty-eight to 72 hours after retrieval, the embryos are ready for transfer back to a woman's uterus. Then a couple waits to see if implantation "takes" and a pregnancy has begun. The process of stimulating ova production with drugs through to the harvesting, fertilizing, and implantation, is referred to as a **cycle**.

Since 1981, more than 33,000 babies born in the United States have been conceived via ART. Sperm banks, **egg donation**, embryo freezing, and surrogacy have been added to the popular lexicon, along with an alphabetic array of high-tech variations on IVF, including GIFT, ZIFT, and ICSI (pronounced ICK-see). **GIFT** (gamete intrafallopian transfer) involves the same course of fertility drugs and egg retrieval as IVF, but the eggs and sperm are returned to a woman's fallopian tube, the natural site for fertilization. **ZIFT** (zygote intrafallopian transfer) is like IVF, except that the zygote (the fertilized egg) is returned to

the fallopian tube, not to the uterus. Some specialists claim that GIFT and ZIFT may increase the likelihood of implantation--the biggest sticking point in ART--by allowing the fertilized egg to follow its natural course to the uterus. Both require that a woman's fallopian tubes be intact.

**ICSI** (intracytoplasmic sperm injection), discovered by accident in Belgium in 1991, is the most recent addition to the ART family. To cause fertilization, an egg is perforated and a single sperm is injected; any resulting embryo is then transferred to the uterus or the fallopian tubes. ICSI represents "a huge advance for treating male infertility," according to Mark Hornstein '77, director of the in vitro fertilization program at Brigham and Women's Hospital.

The success rates for IVF and other ARTs vary widely from clinic to clinic, depending on screening policies (especially regarding age and type of infertility), available medical protocols, and expertise. The average success rate for standard IVF procedures in 1994, the most recent year for nationwide data, was 21.7 percent deliveries per cycle initiated. At Brigham and Women's, the 1994 delivery rate per IVF cycle for women under 40 was 26.44 percent; for women over 40, it was 5.36 percent. At Boston IVF, for standard IVF in the same year, the delivery rate for women under 40 was 16.5 percent; for women over 40, it was 6.41 percent. (The Boston rates apply to cases where there was no male factor infertility involved.) The nationwide success rates for GIFT and ZIFT are higher, at 28.5 percent and 29.1 percent respectively. The highest overall birth rate--46.8 percent--is found with donor eggs, in which the eggs of a fertile, usually younger woman are fertilized in vitro and transferred to the uterus of an infertile woman.

Since the chances of a fertile couple conceiving in any given month are only about 20 percent, ART raises an infertile couple's odds (per attempt) to fertile odds. But conceiving in vivo and in vitro are two quite different things. "Sex usually feels good, and it's easy, and it's free--not so with assisted reproductive techniques," says Susan Pauker, assistant clinical professor of pediatrics and chief of the genetics department at Harvard Pilgrim Health Plan. The median cost of one cycle of reproductive assistance is \$7,800, according to the American Society for Reproductive Medicine. If a couple doesn't succeed at first, they often try three or four times before having a baby or giving up. With little or no insurance coverage available, 85 percent of those fees comes out of patients' pockets.

It is estimated that half the people who suffer infertility never seek a doctor's opinion, and of those who do, approximately 50 percent don't complete the infertility evaluation or the treatment plan. "People think of millions and millions of people getting treatment, when in fact, most people don't go for treatment, and a very, very small percent go for ART," says Alice Domar, director of the Mind/Body Center for Women's Health at Beth Israel Deaconess Medical Center. Many of them hold out hope for a spontaneous cure. Among couples who pursue treatment, some studies show that one third conceive on their own within two to seven years of discontinuing infertility therapy. But Mitchell Rein, assistant professor of ob-gyn and reproductive biology, says, "There's no question that ART is the single most successful treatment for the majority of cases."